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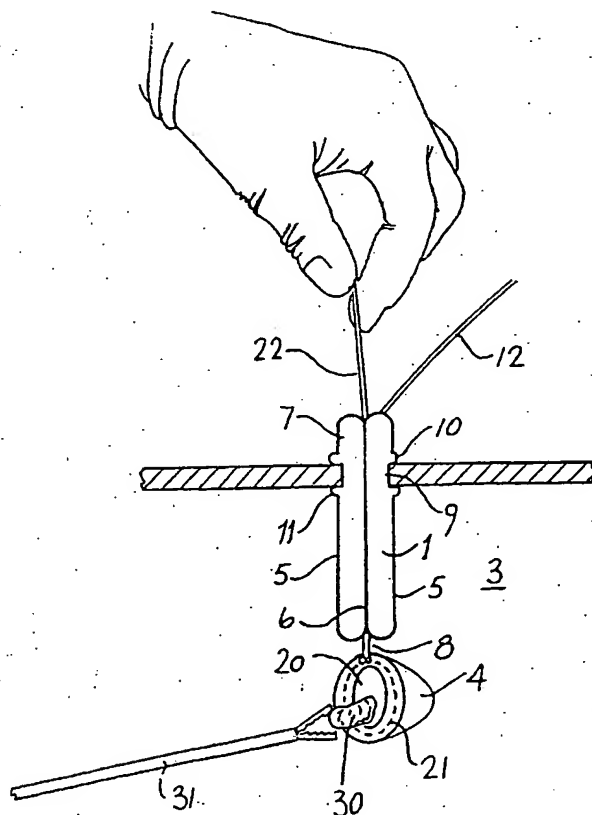
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(54) Title: AN INVAGINATOR APPARATUS



(57) Abstract: An invaginator apparatus for removing a body specimen (30) from a body cavity (3) through an opening (9) to the body cavity (3). The apparatus comprises a pliable evertable sleeve having an outer sleeve section (5), an inner sleeve section (6), and a body specimen receptacle (4) with an open mouth (20). In use, the body specimen (30) is inserted into the receptacle (4), and the mouth (20) is closed by pulling on drawstring (22). Further pulling on the drawstring (22) then invaginates the receptacle (4) with the specimen (30) therein into the sleeve, and both pass out through the body opening (9) by an everting rolling action of the sleeve.

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- 1 -

"An Invaginator Apparatus"Introduction

5 This invention relates to an invaginator apparatus for removal of a body specimen from a body cavity through an opening to the body cavity, for example during laparoscopic surgery.

10 In laparoscopic surgery a surgeon operates through small incisions in an abdominal wall using remotely actuated instruments. The instruments pass through the abdominal wall using sheathing devices called trocars, the working channels of which typically have a diameter ranging from 5 to 25 millimetres. Vision is provided by a laparoscope which is typically 20 to 25 centimetres long and uses fibre-optic technology or a CCD camera to provide the operator with a  
15 picture of the interior of the abdomen. The abdomen is insufflated with a gas such as carbon dioxide or nitrogen to create a bubble effect, and thereby provide a viable working space for the surgeon to perform the surgery in the normally congested abdomen. Insufflation creates a working space known as the pneumoperitoneum.

20 The benefits of laparoscopic surgery are numerous. Recovery times have been shown to be reduced due to the absence of large surgical incisions. This has benefits for the patient, health care organisations and society as a whole. The benefits to the patient are reduced stay in hospital, faster mobilisation and return  
25 to normal activity. The unsightly scars which are often associated with conventional open surgery, are also avoided. The benefits to health care organisations arise due to reduced stay in hospital, which is often the most expensive aspect of health care provision. Society benefits also in the faster return to work and normal activity of the patient.

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- 2 -

The laparoscopic approach has been applied to many surgical procedures such as cholecystectomy, hiato-plasty, gastroplasty, splenectomy, nephrectomy, colectomy, fundoplication and others. Some of these procedures require the removal of body specimens from the abdomen, for example in a  
5 cholecystectomy the gall bladder is removed following resection.

In many situations the body specimen being removed is malignant or exuding fluid, which can potentially cause serious follow-on problems for the patient. For example, it is known that trocar wound openings are susceptible to the  
10 formation of metastatic lesions following contact with cancerous material. Further it is also found that the peritoneal cavity can become inflamed if it exposed to bodily fluids or spilled organ contents that are not sufficiently cleaned out. Other nosocomial conditions may also result from inadvertent contact between healthy tissue and infected or malignant tissue.

15 It is known to insert a body specimen into a specimen retrieval bag for removal of the specimen from a body cavity. US 5,190,555 discloses a rigid elongate member for insertion through a laparoscopic sheath into an abdominal cavity, with a sack secured to the distal end of the rigid member. In use, an excised  
20 body part is placed into the sack, the sack is closed, and the sack and the rigid member are removed from the abdominal cavity.

It is frequently necessary to remove relatively large or irregularly shaped body specimens from a body cavity. However the removal device disclosed in US  
25 5,190,555 suffers from the disadvantage that the size of the specimen that can be removed is limited by the size of the rigid, narrow laparoscopic sheath.

There is a need for an apparatus which facilitates the removal of body specimens of a variety of different sizes and/or shapes from a body cavity in a safe and easy  
30 manner. In particular there is a need for such an apparatus for use during

- 3 -

laparoscopic surgery without loss of insufflation pressure during the removal of a body specimen.

5     Statements of Invention

According to the invention there is provided an invaginator apparatus for removal of a body specimen from a body cavity through an opening to the body cavity comprising: -

10

a sleeve of pliable material having an outer sleeve section and an inner sleeve section;

15

the outer sleeve section and the inner sleeve section defining a chamber therebetween for receiving fluid;

the inner sleeve section defining a lumen having a distal end for receiving a body specimen into the sleeve and a proximal end; and

20

the sleeve being evertable to invaginate the body specimen into the sleeve.

25

In one embodiment of the invention the invaginator apparatus is mountable at a body opening, and the sleeve is evertable to invaginate a body specimen from a body cavity into the sleeve at the lumen distal end, and to deliver the body specimen from the sleeve at the lumen proximal end to a location externally of the body cavity.

30

Preferably the invaginator apparatus comprises retainer means to prevent rolling of the invaginator apparatus from a mounted position at a body opening during eversion of the sleeve. The retainer means may comprise at least one shoulder

- 4 -

for engagement with an edge of a body opening. Ideally the retainer means comprises at least one outer shoulder for engagement with an outer edge of a body opening, and at least one inner shoulder for engagement with an inner edge of a body opening.

5

The shoulder is preferably movable from an introduction configuration to an engagement configuration.

10

In one case the shoulder is expandable to move the shoulder from the introduction configuration to the engagement configuration. Ideally the shoulder is in fluid communication with the chamber.

15

In another case the shoulder is resilient to bias the shoulder from the introduction configuration to the engagement configuration.

The shoulder may be attached to the outer sleeve section.

The shoulder may be integral with the outer sleeve section.

20

Desirably the shoulder extends circumferentially around the sleeve.

25

In a preferred embodiment of the invention the invaginator apparatus comprises means for inflation of the chamber. Ideally the inflation means comprises a port to the chamber, the port being connectable in fluid communication with a source of fluid. Most preferably the inflation means comprises a conduit connectable between the port and a source of fluid.

30

In another embodiment of the invention the apparatus comprises a specimen receptacle for receiving a body specimen therein.



- 5 -

Preferably the receptacle is operably associated with the sleeve for invagination of the receptacle into the sleeve upon eversion of the sleeve.

5 Ideally the receptacle has a mouth for receiving a body specimen into the receptacle. Most preferably the mouth of the receptacle is closable to retain a body specimen within the receptacle.

10 The receptacle may comprise manipulation means to facilitate closure of the mouth. The manipulation means are preferably proximal manipulation means to facilitate closure of the mouth from a location externally of a body. In one case the manipulation means is at least partially flexible. Ideally the manipulation means comprises a drawstring.

15 In a preferred embodiment the receptacle defines a channel around the mouth through which the drawstring may pass.

20 In one case the receptacle has a rim around the mouth, the rim being configured to bias the mouth to an open position. Preferably the rim is at least partially resilient to bias the mouth to the open position.

The receptacle may comprise a plurality of curved walls joined together. The mouth is preferably provided as an opening in one of the curved walls. Most preferably the receptacle comprises three curved walls joined together.

25 In another embodiment of the invention the apparatus comprises a holder for delivering a body specimen to the distal end of the sleeve lumen.

30 The holder may comprise a grasping means which is mounted to the sleeve to grasp a body specimen and deliver it to the distal end of the sleeve lumen. Preferably the grasping means is carried by a handle which extends through the

- 6 -

lumen of the sleeve for remote operation of the grasping means from externally of a body opening.

5 In another case the holder comprises a pocket at the distal end of the sleeve. Preferably the pocket is integral with the sleeve. Preferably the pocket forms an extension of the sleeve. Ideally the pocket has a body specimen receiving opening and the invaginator apparatus includes means for closing the opening. Most preferably the opening is closable by a drawstring. In a preferred case the drawstring extends through the sleeve for remote operation of the drawstring  
10 from externally of a body opening.

In another preferred embodiment of the invention the apparatus comprises an introducer for at least partial introduction of the sleeve into a body cavity, the introducer comprising:-

15

an elongate arm for at least partial introduction through a body opening, the arm defining an internal reception space for the sleeve; and

20

an ejector to deliver the sleeve from an introduction position within the reception space to a position at least partially within the body cavity.

Preferably the ejector comprises a plunger for movement through the reception space to deliver the sleeve from the reception space.

25

The introducer may comprise a seal configured to facilitate extension of an element through the arm in a sealed manner. Ideally the seal includes an aperture to facilitate extension of an element through the arm in a sealed manner.

- 7 -

In another aspect the invention provides a receptacle for removal of a body specimen from a body cavity through an opening to the body cavity, the receptacle defining at least one mouth for receiving a body specimen into the receptacle, and the receptacle comprises proximal manipulation means to facilitate closure of the mouth from a location externally of a body cavity, the manipulation means being at least partially flexible.

In one embodiment of the invention the manipulation means comprises a drawstring. Preferably the receptacle defines a channel around the mouth through which the drawstring may pass.

In one case the receptacle has a rim around the mouth, the rim being configured to bias the mouth to an open position. Ideally the rim is at least partially resilient to bias the mouth to the open position.

In a preferred embodiment the receptacle comprises a plurality of curved walls joined together. Typically the mouth is provided as an opening in one of the curved walls. Ideally the receptacle comprises three curved walls joined together.

The receptacle may be inflatable. Preferably the receptacle is hollow walled for inflation of the receptacle.

According to another aspect of the invention there is provided a method for removing a body specimen from a body cavity through an opening to the body cavity, the method comprising the steps of:-

providing a sleeve of the invention;

introducing the sleeve at least partially through a body opening;

- 8 -

presenting a body specimen to the lumen distal end;

everting the sleeve to invaginate the body specimen into the sleeve; and

5

removing the body specimen from a body cavity through the body opening.

In one embodiment of the invention the method comprises the step of:-

10

mounting the sleeve at a body opening; and

removing a body specimen from a body cavity by everting the sleeve to deliver the invaginated body specimen from the sleeve at the lumen proximal end to a location externally of the body cavity.

15

Preferably the sleeve is mounted at a body opening by positioning the sleeve at least partially within the body opening, and inflating the chamber to engage the outer sleeve section with the body opening walls.

20

The method may comprise the step of moving a retainer means from an introduction configuration to an engagement configuration to engage an edge of a body opening. Ideally the retainer means is expanded to move the retainer means from the introduction configuration to the engagement configuration.

25

In another embodiment of the invention a body specimen is removed from a body cavity by withdrawing the sleeve with the invaginated body specimen therein from the body cavity through a body opening. Ideally the sleeve is introduced completely through a body opening into a body cavity.

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- 9 -

In a preferred embodiment of the invention the method comprises the step of :-

inserting a body specimen into a specimen receptacle; and

5        invaginating the receptacle with the body specimen therein into the sleeve.

The method preferably comprises the step of closing a mouth of the receptacle before invaginating the receptacle into the sleeve.

10

The mouth may be closed by manipulation from a location externally of a body. Ideally the mouth is closed by manipulation of a drawstring.

15

In one case the receptacle is introduced into a body cavity during introduction of the sleeve at least partially through a body opening.

In another case the receptacle is introduced into a body cavity after introduction of the sleeve at least partially through a body opening.

20

In another embodiment of the invention the method comprises the steps of:-

loading the sleeve into an introducer;

introducing the introducer at least partially through a body opening; and

25

delivering the sleeve from the introducer to a position at least partially within a body cavity.

30

The sleeve is preferably inflated during deliverance of the sleeve from the introducer.

- 10 -

In one embodiment of the invention the method is a laparoscopic method.

5 In another embodiment of the invention the method is a hand-assisted laparoscopic method and the method comprises the steps of:-

providing a hand-access device;

10 introducing a hand through the hand-access device into a body cavity;  
and

using the hand to present a body specimen to the lumen distal end.

15 The method of the invention may be for removing a body specimen through a wound opening.

The method of the invention may be for removing a body specimen through a natural body opening.

20 The invention provides an invaginator apparatus for removal of body specimens from a body cavity in such a manner that the entire body specimen is invaginated into the confines of the apparatus so as to prevent the spillage of bodily fluids or organ contents into the body cavity, and/or to prevent seeding or infection in the region of the opening to the body cavity.

25 The invaginator apparatus according to the invention facilitates invagination of a variety of differently sized and/or differently shaped body specimens into the sleeve due to the flexible, deformable nature of the inflated sleeve chamber.

- 11 -

The invention allows the invaginated body specimen to be easily retrieved from the body cavity either through a body opening, such as a trocar wound, a specially created wound or a natural bodily orifice, such as the anus or the vagina.

5

The invaginator apparatus is movable from a low-profile introduction configuration, so as to be capable of easy insertion into a small body opening, to a protruding engagement configuration to ensure that the invaginator apparatus remains securely mounted at the body opening during the sleeve eversion.

10

The invaginator apparatus according to the invention is suitable for use during laparoscopic surgery, or during hand-assisted laparoscopic surgery.

15

The invention also provides a specimen receptacle that has a means of retaining a body specimen to be retrieved within the receptacle so as to permit its removal from the body.

#### Brief Description of the Drawings

20

The invention will be more clearly understood from the following description of some embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which:-

25

Fig. 1 is a side, partially cross-sectional view of an invaginator apparatus according to the invention mounted at a body opening;

Fig. 2(a) is a side view of an introducer for the invaginator apparatus of Fig. 1;

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- 12 -

Fig. 2(b) is a side view of the introducer of Fig. 2(a) assembled;

Fig. 3(a) is a perspective view of a specimen receptacle according to the invention;

5

Fig. 3(b) is a plan view from above of the specimen receptacle of Fig. 3(a);

10

Figs. 4 to 6 are side, partially cross-sectional views of the invaginator apparatus of Fig. 1 in different positions of use;

15

Figs. 7 to 10 are side, partially cross-sectional views illustrating mounting of the invaginator apparatus of Fig. 1 at a body opening using the introducer of Fig. 2(b);

20

Figs. 11 to 16 are perspective views illustrating removal of a body specimen from a body cavity through a body opening using the invaginator apparatus of Fig. 1 and the specimen receptacle of Fig. 3;

25

Fig. 17 is a side, partially cross-sectional view of an invaginator device according to the invention in an uninflated configuration about to be inserted through an incision or trocar site into an abdominal cavity which contains a specimen retrieval bag containing an organ specimen;

Fig. 18 is a side, partially cross-sectional view of the device of Fig. 17 in an uninflated configuration within the margins of the incision in which the jaws of a grasping means are about to close on the specimen retrieval bag containing an organ specimen;



- 13 -

Fig. 19 is a side, partially cross-sectional view of the inflated device within the retracted margins of the incision in which the jaws of the grasping means are closed about the specimen retrieval bag;

5 Fig. 20 is a side, partially cross-sectional view of the device in which the specimen retrieval bag is invaginated within the inflated device, which is located within the margins of the incision;

10 Fig. 21 is a side, partially cross-sectional view of the device removed from the incision and in which the specimen retrieval bag containing the organ specimen is invaginated within the device;

15 Fig. 22 is a perspective view of another invaginator device according to the invention with an integral bag and drawstring in which an inflatable sleeve is within an incision or trocar site, an organ specimen for retrieval being held in jaws of a laparoscopic grasper;

20 Fig. 23 is a perspective view of the device of Fig. 22 in which an organ specimen is placed into the integral bag by the laparoscopic grasper;

Fig. 24 is a perspective view of the device of Fig. 22 inflated with the organ specimen encapsulated within the integral bag and the drawstring pulled taut to close the mouth of the integral bag;

25 Fig. 25 is a perspective view of the device of Fig. 22 illustrating further pulling on the drawstring which results in the invagination of the integral bag and the specimen into the device;

- 14 -

Fig. 26 is a perspective view of the device of Fig. 22 explanted from the incision or trocar site with the integral bag containing the organ specimen invaginated within the device; and

5 Fig. 27 is a side, partially cross-sectional view of another specimen receptacle according to the invention.

#### Detailed Description

10

Referring to the drawings, there is illustrated an invaginator apparatus according to the invention for removing a body specimen, such as a piece of body tissue or a piece of an organ, from a body cavity through an opening to the body cavity. The specimen is typically a diseased piece of body tissue, such as a cancerous growth, or a diseased organ, such as a gall bladder.

15

Referring initially to Figs. 1 to 16, there is illustrated an invaginator apparatus according to the invention, which in this case is suitable for use in pure laparoscopic surgery, or in hand-assisted laparoscopic surgery.

20

The apparatus comprises an invaginator 1 (Fig. 1), an introducer device 2 (Fig. 2) for at least partially introducing the invaginator 1 into a body cavity 3, and a specimen receptacle 4 (Fig. 3).

25

As illustrated in Fig. 1, the invaginator 1 comprises a sleeve of pliable material, such as a polymeric material, having an outer sleeve section 5 and an inner sleeve section 6. The sleeve sections 5, 6 define a chamber 7 therebetween for receiving a fluid, such as pressurised air, and the inner sleeve section 6 defines a lumen 8 extending through the sleeve.

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- 15 -

5 The sleeve is evertable to invaginate a body specimen into a distal end of the sleeve lumen 8. Upon eversion of the sleeve, part of the outer sleeve section 5 rolls inwardly at one end of the sleeve, to become part of the inner sleeve section 6, and simultaneously part of the inner sleeve section 6 rolls outwardly at the other end of the sleeve to become part of the outer sleeve section 5, as illustrated in Figs. 4 to 6. In this case, the invaginator 1 is illustrated everting proximally, however it will be appreciated that eversion of the invaginator 1 distally operates in a similar manner.

10 The sleeve of the invaginator apparatus may be a non-twisted sleeve of the type described in our International patent application published under number WO 00/32120 or may, in some cases be a twisted sleeve of the type described in our International patent application published under number WO 00/32117. The content of both of these patent applications is incorporated herein by reference.

15 The invaginator 1 comprises an inflation tube 12 connected to the outer sleeve section 5 at an inflation port which is in fluid communication with the chamber 7. The inflation tube 12 is connectable to a source of fluid, for example a high pressure air source, to facilitate inflation of the chamber 7 from a low-profile deflated state which enables easy introduction and mounting of the invaginator 1  
20 at an opening 9 to the body cavity 3, to an inflated state in which the outer sleeve section 5 engages the walls of the body opening 9 to mount the invaginator 1 in place in the body opening 9. Inflation of the chamber 7 also assists in retraction of the edges of the body opening 9.

25 The body opening 9 is typically a narrow port opening, as may be formed for example using a trocar, or a similar device to a trocar. The size of the body opening 9 when formed by a trocar, or a similar device is typically in the range of up to 4cm in diameter.

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- 16 -

The invaginator 1 comprises retainer means to prevent the invaginator 1 from rolling from a position mounted in the body opening 9, as illustrated in Fig. 1 and Figs. 4 to 6, either completely into the body cavity 3, or completely out of the body opening 9 during eversion of the sleeve. The retainer means is provided, in this case, by two shoulders extending circumferentially around the sleeve, the shoulders being spaced apart so that an outer shoulder will be positioned to engage an outer edge of the body opening 9 and an inner shoulder will be positioned to engage an inner edge of the body opening 9 when the invaginator 1 is mounted at the body opening 9.

In this case, each shoulder is provided by an inflatable annular ring 10, 11 which is integral with the outer sleeve section 5, each ring 10, 11 being in fluid communication with the chamber 7 so that inflation of the chamber 7 also causes inflation of the rings 10, 11. Upon inflation, the rings 10, 11 move from a low-profile configuration for ease of introduction and mounting of the invaginator 1 in the body opening 9 to a protruding configuration (Fig. 1 and Figs. 4-6) for engagement of each ring 10, 11 with an edge of the body opening 9.

It will be appreciated that other retaining means may be provided in place of one or both of the inflatable rings 10, 11 to equal effect. In particular, one or both shoulders may be provided by a resilient ring attached to the outer sleeve section 5, the ring being biased towards the engagement configuration. In use, the ring may be squeezed into a low-profile, oblong introduction configuration by a user until the ring is suitably positioned adjacent to an edge of the body opening 9. By releasing the resilient ring it will then spring outwardly to the engagement configuration engaging an edge of the body opening 9.

Referring again to Fig. 2, the introducer device 2 comprises an elongate arm 13, the arm 13 defining an internal reception space 14 for the deflated invaginator 1,

- 17 -

and a plunger 15 slidably movable through the reception space 14 in a reciprocating manner to deliver of the invaginator 1 from the reception space 14, in use.

5 As illustrated in Fig. 2(a), the plunger 15 comprises a main body 16 with two outwardly extending fingers 17. The fingers 17 are configured to extend outwardly through two elongate slots 18 in a wall of the arm 13, as illustrated in Fig. 2(b), to allow the user to easily and accurately control the position of the plunger 15 within the reception space 14.

10 A seal 19 is provided at a proximal end of the arm 13. The seal 19 enables an elongate element, such as the inflation tube 12, to be extended in a sealed manner from a point externally of the body cavity 3 through the seal 19 into the reception space 14 past the plunger 15 to the invaginator 1.

15 Referring again to Fig. 3, the specimen receptacle 4 is illustrated. A mouth 20 is provided for receiving a body specimen into the receptacle 4, with a rim 21 surrounding the mouth 20. The rim 21 is configured to bias the mouth 20 to the open position illustrated in Fig. 3(a) for ease of insertion of body specimens into the receptacle 4. In one case the rim 21 is at least partially resilient to bias the  
20 mouth 20 to an open position.

As illustrated in Fig. 3(b), the receptacle 4 is formed by joining three curved walls 41, 42, 43 together to define a "tent-like" bag for receiving a body specimen therein. The mouth 20 is provided by an opening in wall 43, in this  
25 case. The tent shape of the receptacle 4 assists in the insertion of body specimens into the receptacle 4 by maintaining the mouth 20 in an open configuration.

- 18 -

5 A flexible drawstring 22 is looped through a channel in the rim 21 around the mouth 20 to facilitate selective closure of the mouth 20 by a user to safely retain any inserted body specimens within the receptacle 4. The drawstring 22 may be lead from the body cavity 3 out through the lumen 8 of the invaginator 1 to a point externally of the cavity 3. In this manner a user can selectively close the mouth 20 from a proximal position externally of the body cavity 3. The mouth 20 may be opened using a laparoscopic grasper, if desired.

10 In use, and referring initially to Figs. 7 to 10, the invaginator 1 in a deflated state is loaded into the reception space 14 of the introducer device 2. The plunger 15 is retracted to enable substantially all of the deflated invaginator 1 to be housed within the reception space 14. A portion of the distal end of the invaginator 1 may protrude from the distal end of the arm 13 of the introducer device 2, as illustrated in Fig. 7. The inflation tube 12 is led from the inflation port, where it is connected to the outer sleeve section 5, through an aligned aperture in the plunger 15, and out through the seal 19 (Fig. 7).

20 The distal end of the loaded introducer device 2 is then introduced into the body opening 9, which has been created prior to the introduction of the device 2, for example by a separate trocar, or by a scalpel.

25 The loaded introducer device 2 is advanced through the body opening 9 until the deflated inner ring 11 is adjacent to the inner edge of the body opening 9 (Fig. 7). By pressing against fingers 17 the plunger 15 is moved through the reception space 14 until the plunger 15 engages the deflated invaginator 1. The chamber 7 is then inflated and simultaneously the arm 13 is retracted out of the body opening 9 while maintaining the position of the plunger 15 by pressing against fingers 17. As illustrated in Figs. 8 and 9, this combined inflation and ejection action, ensures that the invaginator 1 is correctly delivered within the narrow body opening 9, with the inflated retainer rings 10, 11 protruding outwardly to

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- 19 -

engage the outer and inner edges of the body opening 9 respectively. This procedure ensures that the invaginator 1 is securely mounted in the body opening 9 (Fig. 10).

5 Referring now to Figs. 11 to 16, the receptacle 4 is inserted into the lumen 8 of the invaginator 1 and passed through the lumen 8 and into the body cavity 3 by a combination of sleeve eversion and pushing of the receptacle 4 through the sleeve lumen 8.

10 Alternatively, the receptacle 4 may be loaded into the reception space 14 of the introducer device 2 distally of the deflated invaginator 1. Both the invaginator 1 and the receptacle 4 may be introduced through the body opening 9 together in a manner similar to that described previously with reference to Figs. 7 to 10. As the chamber 7 is inflated and the arm 13 is retracted, the receptacle 4 is pushed  
15 out of the reception space 14 and delivered into the body cavity 3.

In either case, the user maintains a proximal hold on the flexible drawstring 22, so that the drawstring 22 extends from a location externally of the body cavity 3 through the invaginator lumen 8, and through the channel in the rim 21 of the  
20 receptacle 4 which is located within the body cavity 3, as illustrated in Fig. 11. Inflation of the chamber 7 ensures that the body opening 9 is gas-tightly sealed, thus pneumoperitoneum in the body cavity 3 will be maintained, for example during pure laparoscopic surgery, or during hand-assisted laparoscopic surgery.

25 With the receptacle 4 positioned within the body cavity 3 with the mouth 20 in an open position, a body specimen 30 is presented to the open mouth 20 (Fig. 12), and inserted through the mouth 20 and into the receptacle 4 (Fig. 13). A typical body specimen is a gall bladder, or a kidney. A variety of differently sized specimen receptacles may be provided to accommodate differently sized  
30 body specimens.

- 20 -

5 The specimen 30 may be gripped for insertion into the receptacle 4 by any suitable means, for example by a laparoscopic grasping instrument 31, as illustrated in Figs. 12 and 13, or for example by using a hand inserted into the body cavity 3 through a hand-access device during a hand-assisted laparoscopy procedure.

10 The drawstring 22 is then pulled proximally by the user from the location externally of the body opening 3, thereby collapsing the rim 21 down to close the mouth 20 and safely retain the body specimen 30 within the receptacle 4 (Fig. 14). The closed receptacle 4 is drawn proximally towards the inflated invaginator 1 by pulling the drawstring 22 proximally through the sleeve lumen 8 until the closed receptacle 4 engages the distal end of the sleeve. No eversion of the sleeve occurs during this initial pulling of the drawstring 22 through the sleeve lumen 8 due to the flexible nature of the drawstring 22. Further drawing of the receptacle 4 proximally then causes the invaginator 1 to evert and thereby invaginate the receptacle 4 with the specimen 30 therein into the sleeve (Fig. 15).

20 The sleeve everts proximally until the receptacle 4 has passed through the full length of the sleeve lumen 8. When the receptacle 4 reaches the proximal end of the lumen 8, the receptacle 4 is delivered out of the invaginator 1 to a location externally of the body cavity 3, as illustrated in Fig. 16, by the user pulling the receptacle 4 proximally.

25 The sleeve of the invaginator 1 everts proximally without the invaginator 1 rolling from the mounted position in the body opening 9 due to the presence of the inflated retaining rings 10, 11, which are in secure engagement with the edges of the body opening 9.



- 21 -

The receptacle 4 may then be opened and the specimen 30 may be removed for examination, or for testing, or for disposal, or for any other purpose, as desired.

5 Pneumoperitoneum in the body cavity 3 is maintained throughout the insertion procedure due to the proximal seal 19 provided by the introducer 2, and pneumoperitoneum is maintained throughout the invagination and removal procedure due to the inflated seal at the body opening 9 provided by the invaginator 1. This is particularly important when the invaginator 1 is used in a laparoscopic surgical application, or in a hand-assisted laparoscopic surgical  
10 application.

The drawstring 22 enables a user to close the mouth 20 of the receptacle 4 to safely retain body specimens 30 within the receptacle 4, and to invaginate the receptacle 4 into the sleeve. By leading the drawstring 22 out of the body cavity  
15 3 through the sleeve lumen 8, the manipulation of the receptacle 4 can be performed from a proximal location externally of the body cavity 3. The flexible nature of the drawstring 22 ensures that the passage of the drawstring 22 through the sleeve lumen 8 does not adversely affect the sealing of the body opening 9 which is effected by the inflated sleeve. In addition the flexibility of the  
20 drawstring 22 ensures that no rolling of the sleeve occurs until the receptacle 4 is invaginated into the sleeve.

As the receptacle 4 with the specimen 30 therein passes through the everting invaginator 1, the inflation pressure within the chamber 7, and the inward pressure exerted by the edges of the body opening 9 act to compress and elongate  
25 the invaginated body specimen 30. This process assists in passage of the specimen 30 through the body opening 9. Further relatively large, or irregularly shaped body specimens 30 are elongated and compressed by the invaginator 1, and thus can easily pass through the body opening 9 using the invaginator apparatus of the invention. This is particularly advantageous in the case of  
30

- 22 -

laparoscopic surgery, or in hand-assisted laparoscopic surgery, where the body opening 9 is typically narrow. A typical laparoscopic body opening may be sized in the range of up to 4cm in diameter.

5 In addition, the passage of the specimen 30 through the inflated invaginator 1 provides an outward retraction force on the edges of the body opening 9. In this manner, the invaginator 1 helps to ease passage of the specimen 30 through the body opening 9 by at least partially retracting the edges of the body opening 9 to widen the body opening 9. The invaginator 1 thus facilitates removal of  
10 relatively large, or irregularly shaped body specimens 30 from the cavity 3.

The body specimen 30 is completely invaginated within the sleeve during removal from the body cavity 3. In this manner, the invaginator 1 protects  
15 against contamination of the body cavity 3 and/or of the body opening 9 due to the body specimen 30.

Large forces are not required to invaginate and remove the body specimen 30 from the body cavity 3 using the invention due to the frictionless rolling which occurs as the specimen 30 passes through the everting sleeve.  
20

In an alternative procedure of use, the invaginator 1 is not mounted at the body opening 9. Instead the invaginator 1 is introduced completely through the body opening 9 so that the invaginator 1 is fully located within the body cavity 3. The invaginator 1 may be introduced through the body opening 9 using a cannula, or  
25 using a hand-access device, or any other suitable introduction means.

When the invaginator 1 is positioned within the body cavity 3 as desired, the chamber 7 is inflated. A body specimen 30 is then presented to the distal end of the lumen 8 and the sleeve is everted to invaginate the specimen 30 into the

- 23 -

sleeve, in a manner similar to that described previously with reference to Figs. 14 and 15.

5 A receptacle 4 may be used to retain the specimen 30 before invagination into the sleeve.

10 In this case, the sleeve is everted until the specimen 30 is completely invaginated into the sleeve. The invaginator 1 with the specimen 30 therein is then withdrawn from the body cavity 3 through the body opening 9 by the user. When the invaginator 1 and the specimen 30 are fully withdrawn to a location externally of the body cavity 3, the sleeve may be everted to deliver the specimen 30 out of the sleeve lumen 8. The specimen 30 may then be examined, or tested, or disposed of, or dealt with in any other desired manner.

15 It will be understood from the invention that morcellation of the body specimen and piecemeal removal of the morcellated specimen may be performed using the invaginator apparatus and/or the specimen receptacle according to the invention.

20 The invaginator apparatus according to the invention is suitable for removing a body specimen through a natural body opening, such as the vagina or the anus, or for removing a body specimen through a wound opening, such as a trocar puncture site.

25 It will be appreciated that the body specimen receptacle 4 according to the invention is suitable for use in a variety of different applications, and the specimen receptacle 4 is not constrained to be used with the invaginator 1.

- 24 -

It will also be appreciated that other body specimen receptacles may be used with the invaginator 1, if desired. The invaginator 1 is not constrained to be used with the specimen receptacle 4 according to the invention.

5 Referring now to Figs. 17 to 21 there is illustrated an invaginator device 101 according to another embodiment of the invention. The device 101 consists of a double-layer, evertable, inflatable polymeric sleeve 102 attached to an elongated rod 103. The rod 103 has a grasping means 104 at its distal end and a handle 106 at its proximal end. The handle 106 operates the grasping means 104 using  
10 actuating means that pass through the centre of the rod 103. The device 101 is constructed in such a manner so that the rod 103 passes through the central lumen of the sleeve 102 and both components are joined at their distal ends with the grasping means 104 protruding from the distal end of the sleeve 102. An inflation means is provided to inflate the inflatable polymeric sleeve through an  
15 inlet line 105.

In use, the device 101 is inserted into an abdominal space through an incision 111 that is located in close proximity to a body specimen, or organ specimen 110 to be removed. In this case, the device 101 is not inserted wholly into the abdominal space but remains within the margins of the incision 111. Preferably,  
20 the device 101 is inserted into a used trocar site or into a trocar site that has been surgically extended. The device 101 is pushed into the abdominal space until the grasping means 104 is close enough to grasp the organ specimen 110 (Fig. 18). Preferably the organ specimen 110 is within a specimen retrieval bag 112. When  
25 a firm grip has been achieved on the organ specimen 110 or the retrieval bag 112 the double-layer, evertable, inflatable polymeric sleeve 102 is inflated by passing a fluid through the inlet line 105 (Fig. 19). Inflation pressure within the sleeve 102 causes the margins of the incision 111 to be retracted. The grasping rod 103 is then withdrawn from the abdominal space. This action causes the sleeve 102 to  
30 evert, thus invaginating the organ specimen 110 into the sleeve 102 (Fig. 20).

- 25 -

Further withdrawal of the rod 103 cause the organ specimen 110 to be extracted from the abdominal space and the incision 111 (Fig. 21).

5 Referring now to Figs. 22 to 26 there is illustrated another invaginator device 120 according to the invention. In this case the grasping rod 103 is absent and the sleeve 102 has an integral organ retrieval bag 121. The integral bag 121 consists of a single-layer extension of the distal end of the sleeve 102 and has a drawstring 122 at its open end. The drawstring 122 passes through loops at the end of the integral bag 121, passes back through the lumen of the sleeve 102 and  
10 exits at its proximal opening.

In use, the device 120 is inserted by passing the sleeve 102 through an incision 111 into the abdominal space such that it remains within the margins of the incision 111 as in the previous embodiment. The organ specimen 110 to be  
15 removed may be manipulated into the integral bag 121 using laparoscopic graspers 130 (Fig. 23) or similar techniques. When the specimen 110 is in the bag 121 the sleeve 102 is inflated to achieve rigidity and the drawstring 122 is pulled taut to close the bag 121 (Fig. 24). Further pulling on the drawstring 122 will cause the integral bag 121 to become invaginated within the inflated sleeve 102  
20 (Fig. 25) where it will pass through the central lumen of the sleeve 102 until it emerges from the margins of the incision 111 in the abdominal cavity (Fig. 26).

Referring to Fig. 27 there is illustrated another body specimen receptacle 201 according to the invention. The specimen receptacle 201 comprises a sleeve of  
25 pliable material which encloses an inflatable chamber 206. The sleeve has a U-shape in an uninflated state, as illustrated in Fig. 27, and a substantially O-shape in an inflated state.

In use, the sleeve is positioned extending from outside an opening 204 to a body  
30 cavity 203, through the opening 204 and into the cavity 203, as illustrated in Fig.

- 26 -

27. A body specimen 205 is then placed in the U-shaped, uninflated sleeve, and the chamber 206 is inflated by passing a fluid through inflation tube 202 to move the sleeve to the O-shape, and thereby deliver the specimen 205 up and out of the body cavity 203 through the body opening 204.

5

The invention is not limited to the embodiments hereinbefore described which may be varied in construction and detail.

- 27 -

Claims

1. An invaginator apparatus for removal of a body specimen from a body cavity through an opening to the body cavity comprising: -

5 a sleeve of pliable material having an outer sleeve section and an inner sleeve section;

10 the outer sleeve section and the inner sleeve section defining a chamber therebetween for receiving fluid;

the inner sleeve section defining a lumen having a distal end for receiving a body specimen into the sleeve and a proximal end; and

15 the sleeve being evertable to invaginate the body specimen into the sleeve.

2. Apparatus as claimed in claim 1 wherein the invaginator apparatus is mountable at a body opening, and the sleeve is evertable to invaginate a body specimen from a body cavity into the sleeve at the lumen distal end, and to deliver the body specimen from the sleeve at the lumen proximal end to a location externally of the body cavity.

- 25 3. Apparatus as claimed in claim 2 wherein the invaginator apparatus comprises retainer means to prevent rolling of the invaginator apparatus from a mounted position at a body opening during eversion of the sleeve.

4. Apparatus as claimed in claim 3 wherein the retainer means comprises at least one shoulder for engagement with an edge of a body opening.

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- 28 -

- 5
5. Apparatus as claimed in claim 4 wherein the retainer means comprises at least one outer shoulder for engagement with an outer edge of a body opening, and at least one inner shoulder for engagement with an inner edge of a body opening.
6. Apparatus as claimed in claim 4 or 5 wherein the shoulder is movable from an introduction configuration to an engagement configuration.
- 10
7. Apparatus as claimed in claim 6 wherein the shoulder is expandable to move the shoulder from the introduction configuration to the engagement configuration.
8. Apparatus as claimed in claim 7 wherein the shoulder is in fluid communication with the chamber.
- 15
9. Apparatus as claimed in claim 6 wherein the shoulder is resilient to bias the shoulder from the introduction configuration to the engagement configuration.
- 20
10. Apparatus as claimed in any of claims 4 to 9 wherein the shoulder is attached to the outer sleeve section.
11. Apparatus as claimed in any of claims 4 to 9 wherein the shoulder is integral with the outer sleeve section.
- 25
12. Apparatus as claimed in any of claims 4 to 11 wherein the shoulder extends circumferentially around the sleeve.
13. Apparatus as claimed in any preceding claim wherein the invaginator apparatus comprises means for inflation of the chamber.
- 30



- 29 -

14. Apparatus as claimed in claim 13 wherein the inflation means comprises a port to the chamber, the port being connectable in fluid communication with a source of fluid.
- 5 15. Apparatus as claimed in claim 14 wherein the inflation means comprises a conduit connectable between the port and a source of fluid.
- 10 16. Apparatus as claimed in any preceding claim comprising a specimen receptacle for receiving a body specimen therein.
- 15 17. Apparatus as claimed in claim 16 wherein the receptacle is operably associated with the sleeve for invagination of the receptacle into the sleeve upon eversion of the sleeve.
18. Apparatus as claimed in claim 16 or 17 wherein the receptacle has a mouth for receiving a body specimen into the receptacle.
- 20 19. Apparatus as claimed in claim 18 wherein the mouth of the receptacle is closable to retain a body specimen within the receptacle.
20. Apparatus as claimed in claim 19 wherein the receptacle comprises manipulation means to facilitate closure of the mouth.
- 25 21. Apparatus as claimed in claim 20 wherein the manipulation means are proximal manipulation means to facilitate closure of the mouth from a location externally of a body.
- 30 22. Apparatus as claimed in claim 20 or 21 wherein the manipulation means is at least partially flexible.

- 30 -

23. Apparatus as claimed in claim 22 wherein the manipulation means comprises a drawstring.
- 5 24. Apparatus as claimed in claim 23 wherein the receptacle defines a channel around the mouth through which the drawstring may pass.
25. Apparatus as claimed in any of claims 18 to 24 wherein the receptacle has a rim around the mouth, the rim being configured to bias the mouth to an open position.
- 10 26. Apparatus as claimed in claim 25 wherein the rim is at least partially resilient to bias the mouth to the open position.
- 15 27. Apparatus as claimed in any of claims 16 to 26 wherein the receptacle comprises a plurality of curved walls joined together.
28. Apparatus as claimed in claim 27 wherein the mouth is provided as an opening in one of the curved walls.
- 20 29. Apparatus as claimed in claim 27 or 28 wherein the receptacle comprises three curved walls joined together.
- 25 30. Apparatus as claimed in any preceding claim comprising a holder for delivering a body specimen to the distal end of the sleeve lumen.
31. Apparatus as claimed in claim 30 where the holder comprises a grasping means which is mounted to the sleeve to grasp a body specimen and deliver it to the distal end of the sleeve lumen.

- 31 -

32. Apparatus as claimed in claim 31 wherein the grasping means is carried by a handle which extends through the lumen of the sleeve for remote operation of the grasping means from externally of a body opening.
- 5 33. Apparatus as claimed in any of claims 30 to 32 wherein the holder comprises a pocket at the distal end of the sleeve.
34. Apparatus as claimed in claim 33 wherein the pocket is integral with the sleeve.
- 10 35. Apparatus as claimed in claim 34 wherein the pocket forms an extension of the sleeve.
- 15 36. Apparatus as claimed in any of claims 33 to 35 wherein the pocket has a body specimen receiving opening and the invaginator apparatus includes means for closing the opening.
- 20 37. Apparatus as claimed in claim 36 wherein the opening is closable by a drawstring.
38. Apparatus as claimed in claim 37 wherein the drawstring extends through the sleeve for remote operation of the drawstring from externally of a body opening.
- 25 39. Apparatus as claimed in any preceding claim wherein the apparatus comprises an introducer for at least partial introduction of the sleeve into a body cavity, the introducer comprising:-

- 32 -

an elongate arm for at least partial introduction through a body opening, the arm defining an internal reception space for the sleeve; and

5           an ejector to deliver the sleeve from an introduction position within the reception space to a position at least partially within the body cavity.

10           40. Apparatus as claimed in claim 39 wherein the ejector comprises a plunger for movement through the reception space to deliver the sleeve from the reception space.

15           41. Apparatus as claimed in any of claims 39 or 40 wherein the introducer comprises a seal configured to facilitate extension of an element through the arm in a sealed manner.

42. Apparatus as claimed in claim 41 wherein the seal includes an aperture to facilitate extension of an element through the arm in a sealed manner.

20           43. An invaginator apparatus substantially as hereinbefore described with reference to the accompanying drawings.

25           44. A receptacle for removal of a body specimen from a body cavity through an opening to the body cavity, the receptacle defining at least one mouth for receiving a body specimen into the receptacle, and the receptacle comprises proximal manipulation means to facilitate closure of the mouth from a location externally of a body cavity, the manipulation means being at least partially flexible.

- 33 -

45. A receptacle as claimed in claim 44 wherein the manipulation means comprises a drawstring.
- 5 46. A receptacle as claimed in claim 45 wherein the receptacle defines a channel around the mouth through which the drawstring may pass.
47. A receptacle as claimed in any of claims 44 to 46 wherein the receptacle has a rim around the mouth, the rim being configured to bias the mouth to an open position.
- 10 48. A receptacle as claimed in claim 47 wherein the rim is at least partially resilient to bias the mouth to the open position.
49. A receptacle as claimed in any of claims 44 to 48 wherein the receptacle comprises a plurality of curved walls joined together.
- 15 50. A receptacle as claimed in claim 49 wherein the mouth is provided as an opening in one of the curved walls.
- 20 51. A receptacle as claimed in claim 49 or 50 wherein the receptacle comprises three curved walls joined together.
52. A receptacle as claimed in any of claims 44 to 51 wherein the receptacle is inflatable.
- 25 53. A receptacle as claimed in claim 52 wherein the receptacle is hollow walled for inflation of the receptacle.
54. A receptacle substantially as hereinbefore described with reference to the accompanying drawings.
- 30

- 34 -

55. A method for removing a body specimen from a body cavity through an opening to the body cavity, the method comprising the steps of:-

5                   providing a sleeve as claimed in any of claims 1 to 43;  
  
                  introducing the sleeve at least partially through a body opening;  
  
                  presenting a body specimen to the lumen distal end;  
10                   everting the sleeve to invaginate the body specimen into the sleeve;  
                  and  
  
                  removing the body specimen from a body cavity through the body  
15                   opening.

56. A method as claimed in claim 55 wherein the method comprises the step of:-

20                   mounting the sleeve at a body opening; and  
  
                  removing a body specimen from a body cavity by everting the  
                  sleeve to deliver the invaginated body specimen from the sleeve at  
                  the lumen proximal end to a location externally of the body cavity.

25                   57. A method as claimed in claim 56 wherein the sleeve is mounted at a body  
                  opening by positioning the sleeve at least partially within the body  
                  opening, and inflating the chamber to engage the outer sleeve section  
                  with the body opening walls.

30

- 35 -

58. A method as claimed in claim 56 or 57 wherein the method comprises the step of moving a retainer means from an introduction configuration to an engagement configuration to engage an edge of a body opening.
59. A method as claimed in claim 58 wherein the retainer means is expanded to move the retainer means from the introduction configuration to the engagement configuration.
60. A method as claimed in claim 55 wherein a body specimen is removed from a body cavity by withdrawing the sleeve with the invaginated body specimen therein from the body cavity through a body opening.
61. A method as claimed in claim 60 wherein the sleeve is introduced completely through a body opening into a body cavity.
62. A method as claimed in any of claims 55 to 61 wherein the method comprises the step of :-
- inserting a body specimen into a specimen receptacle; and
- invaginating the receptacle with the body specimen therein into the sleeve.
63. A method as claimed in claim 62 wherein the method comprises the step of closing a mouth of the receptacle before invaginating the receptacle into the sleeve.
64. A method as claimed in claim 63 wherein the mouth is closed by manipulation from a location externally of a body.

- 36 -

65. A method as claimed in claim 63 or 64 wherein the mouth is closed by manipulation of a drawstring.
- 5 66. A method as claimed in any of claims 62 to 65 wherein the receptacle is introduced into a body cavity during introduction of the sleeve at least partially through a body opening.
- 10 67. A method as claimed in any of claims 62 to 65 wherein the receptacle is introduced into a body cavity after introduction of the sleeve at least partially through a body opening.
- 15 68. A method as claimed in any of claims 55 to 67 wherein the method comprises the steps of:-  
loading the sleeve into an introducer;  
introducing the introducer at least partially through a body opening; and  
20 delivering the sleeve from the introducer to a position at least partially within a body cavity.
- 25 69. A method as claimed in claims 57 and 68 wherein the sleeve is inflated during deliverance of the sleeve from the introducer.
70. A laparoscopic method as claimed in any of claims 55 to 69.
- 30 71. A hand-assisted laparoscopic method as claimed in any of claims 55 to 69 wherein the method comprises the steps of:-



- 37 -

providing a hand-access device;

introducing a hand through the hand-access device into a body cavity; and

5

using the hand to present a body specimen to the lumen distal end.

72. A method for removing a body specimen through a wound opening as claimed in any of claims 55 to 71.

10

73. A method for removing a body specimen through a natural body opening as claimed in any of claims 55 to 71.

15

74. A method substantially as hereinbefore described with reference to the accompanying drawings.

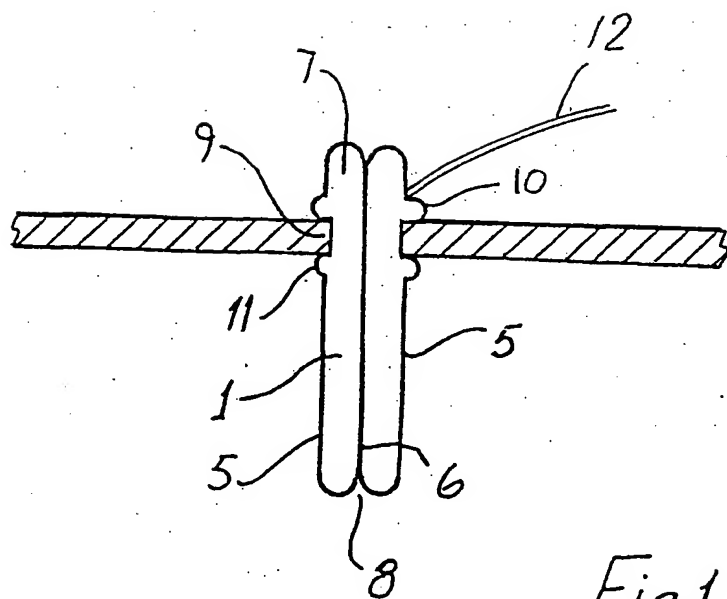


Fig. 1

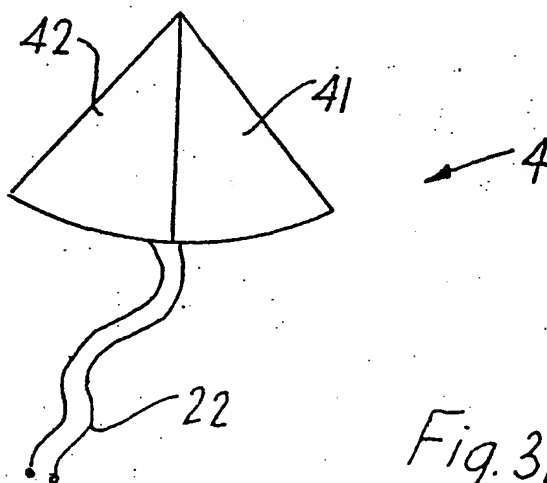


Fig. 3(b)

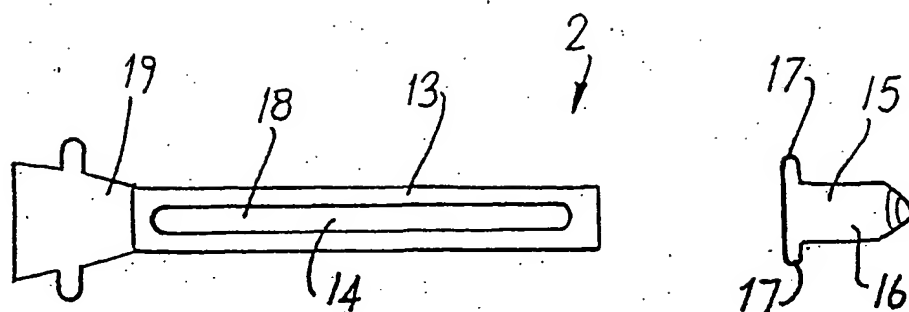


Fig. 2(a)

Fig. 2(b)

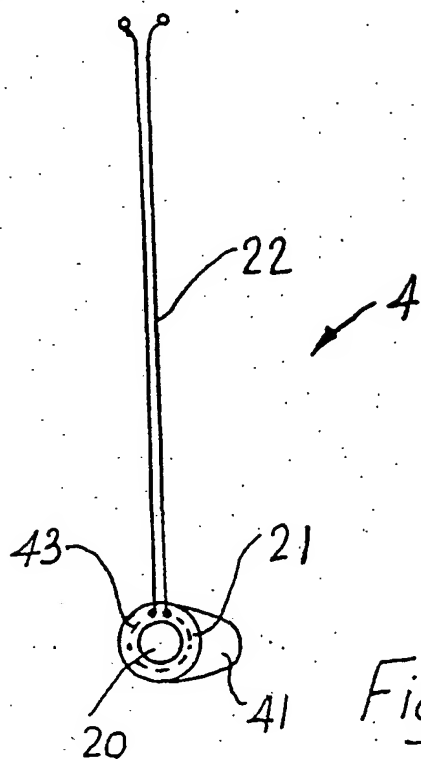
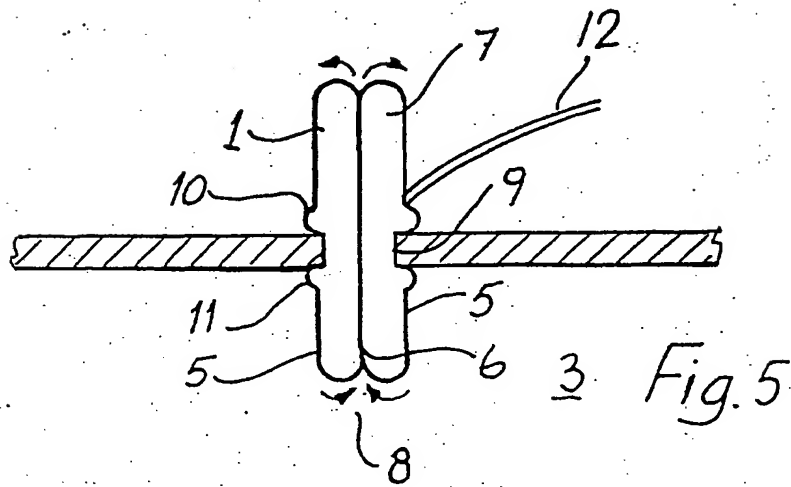
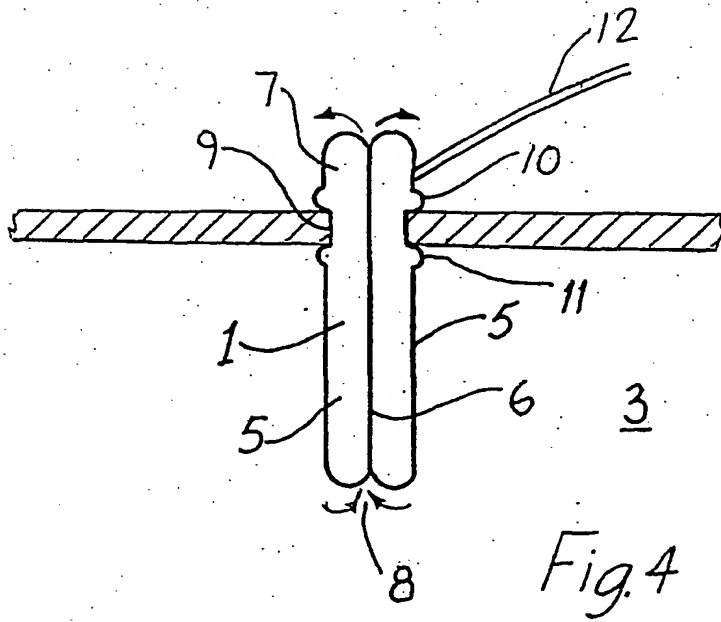


Fig. 3(a)



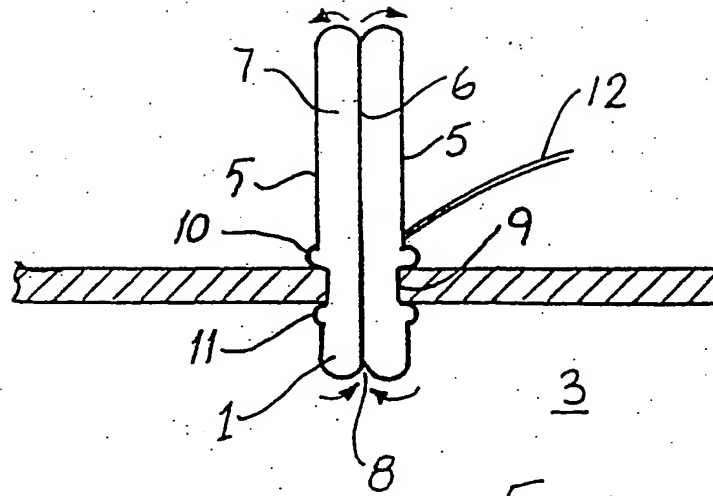


Fig. 6

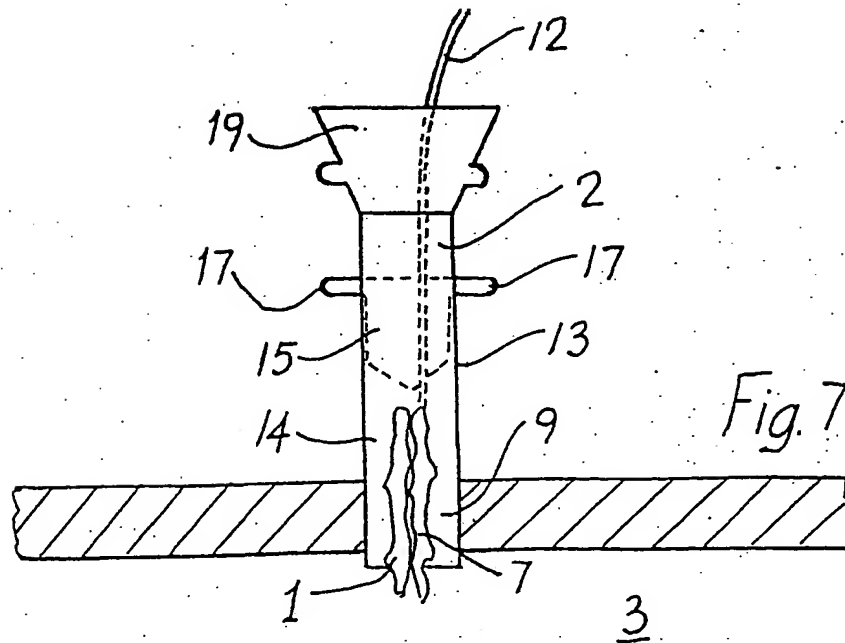
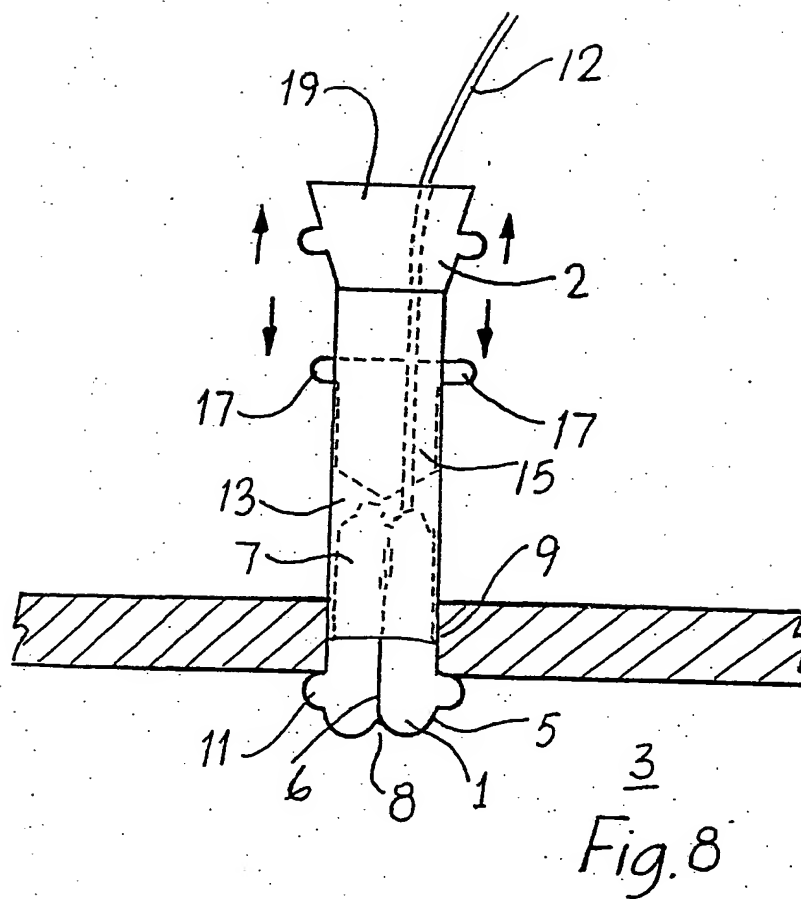


Fig. 7



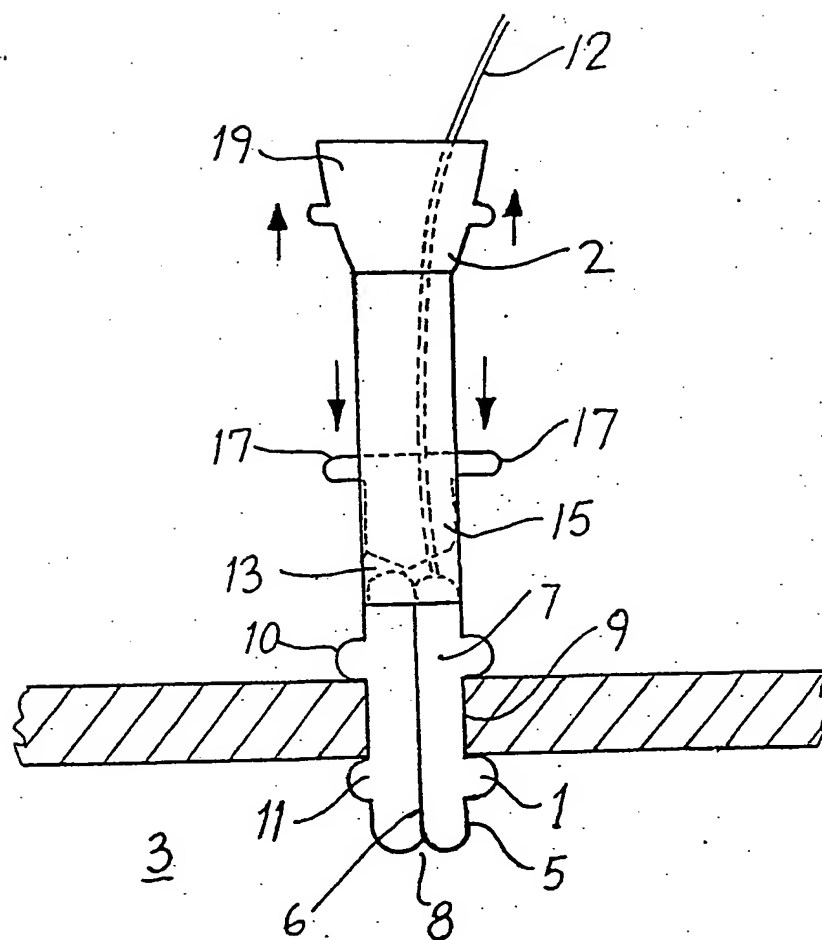


Fig. 9

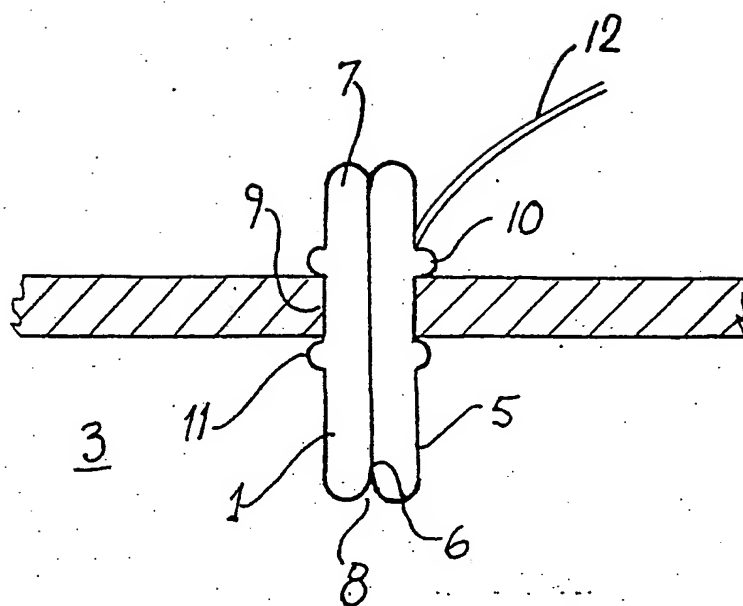
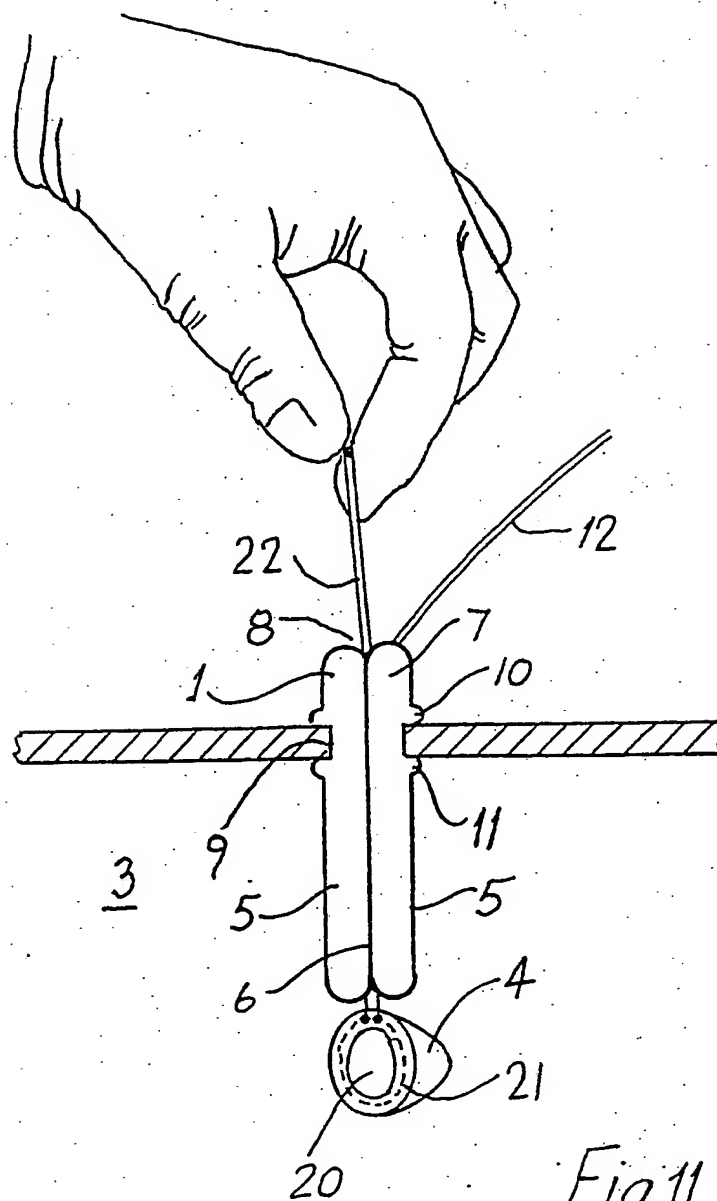
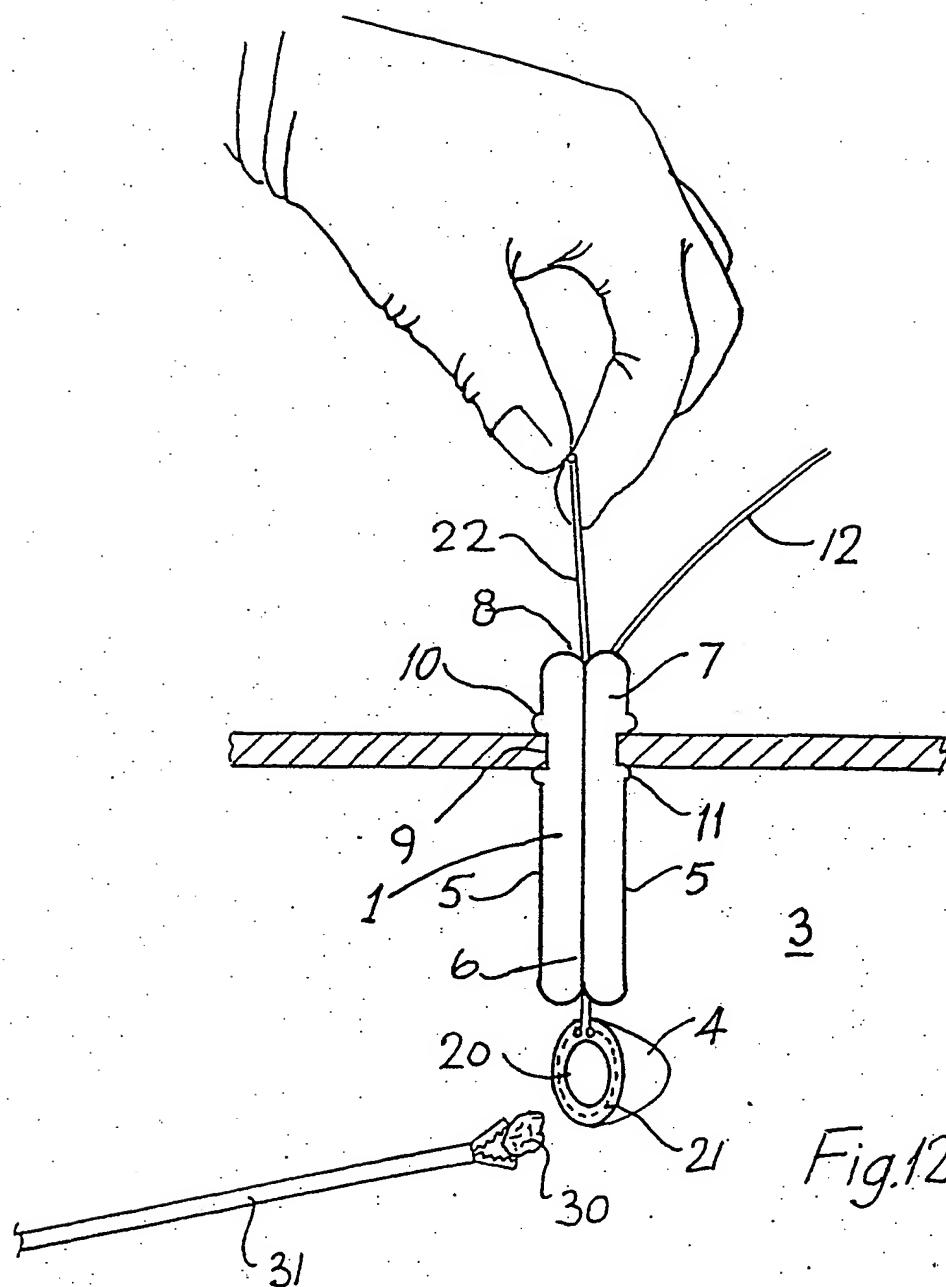
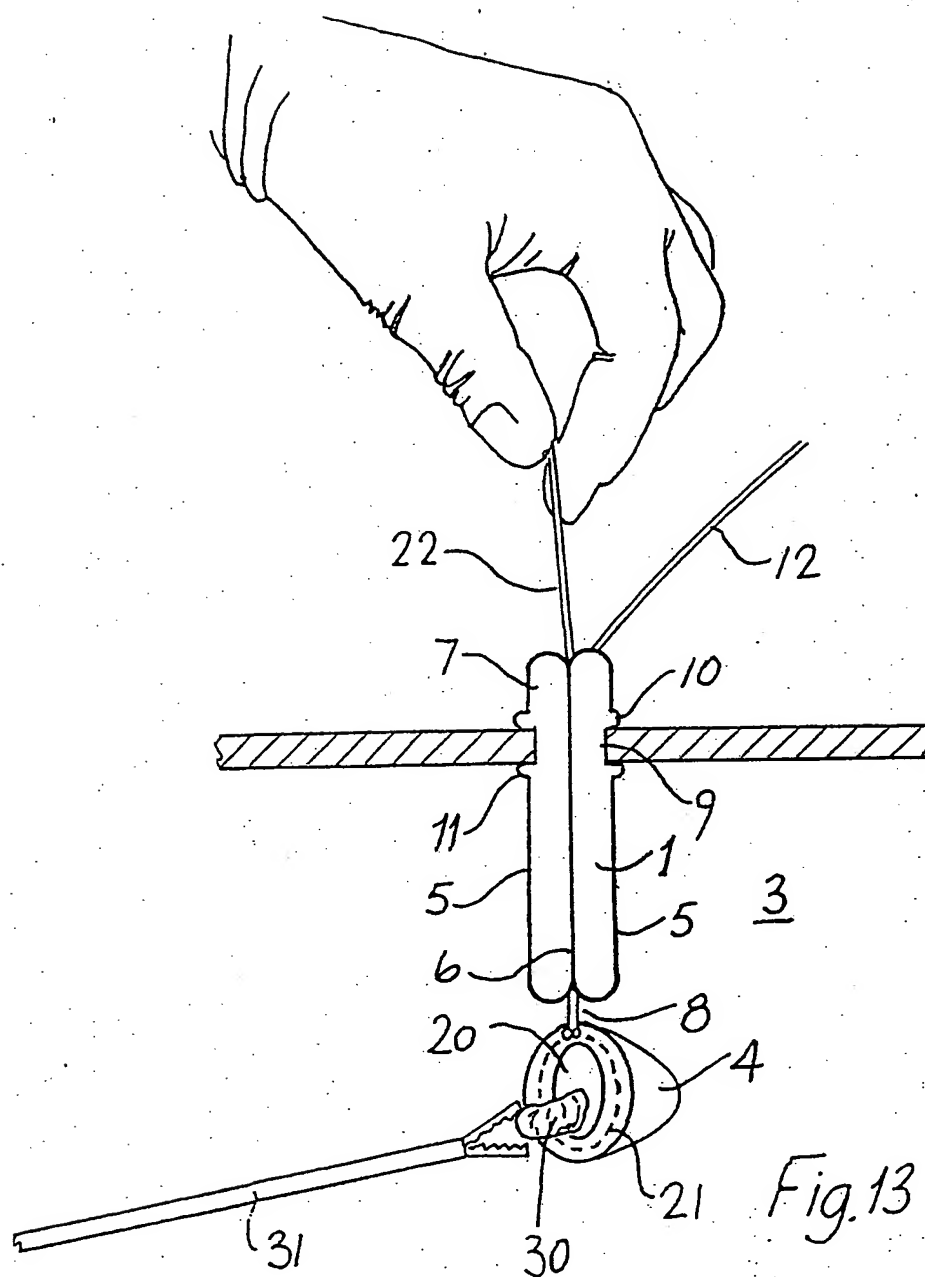


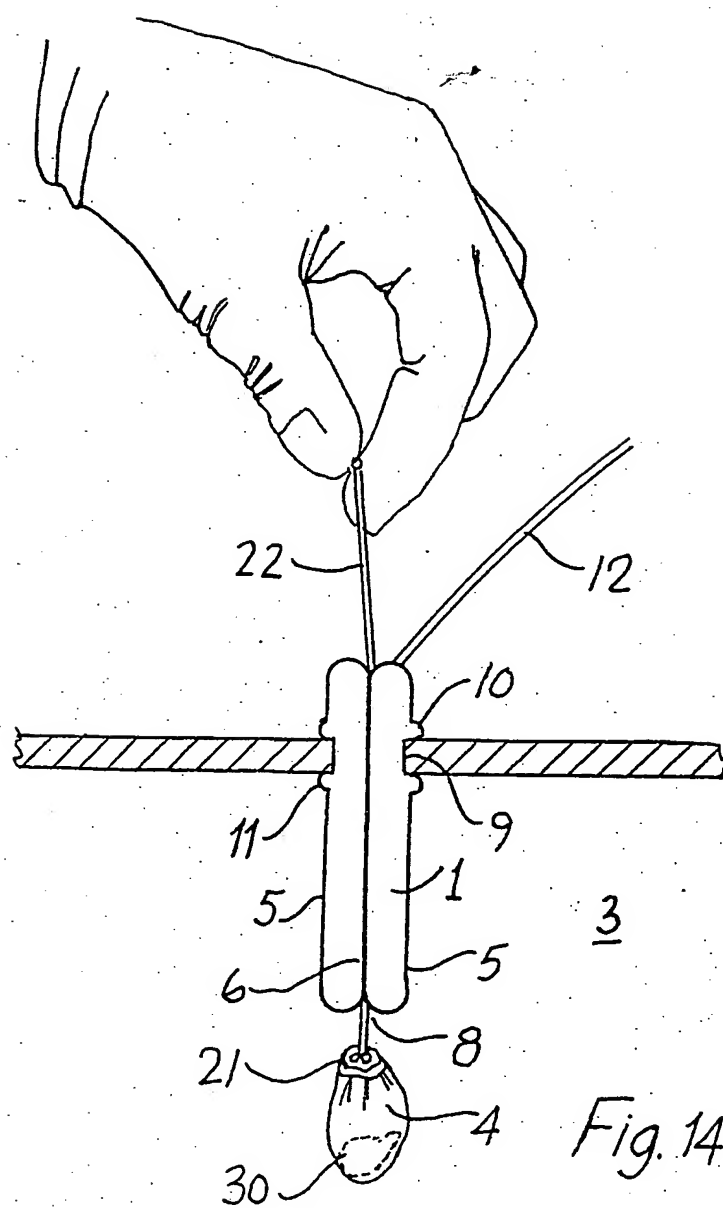
Fig. 10

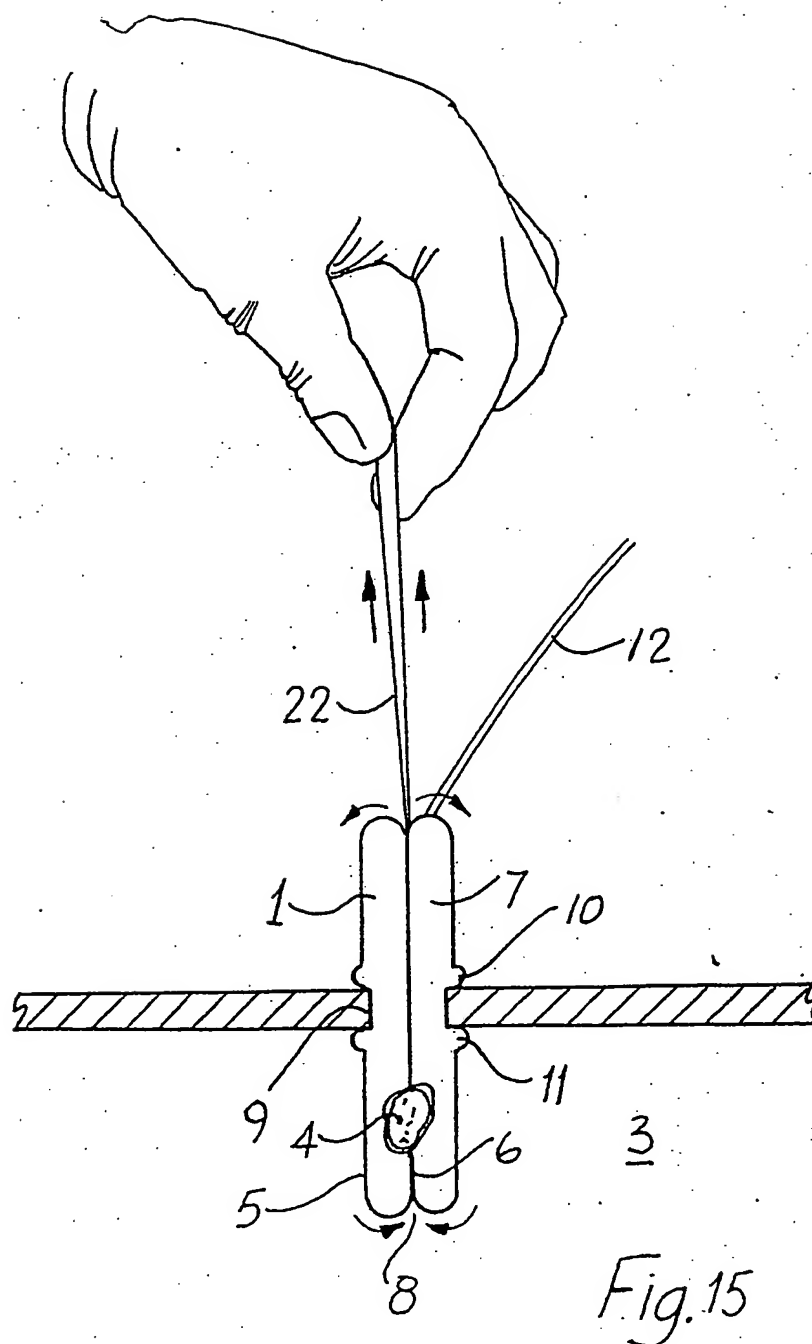












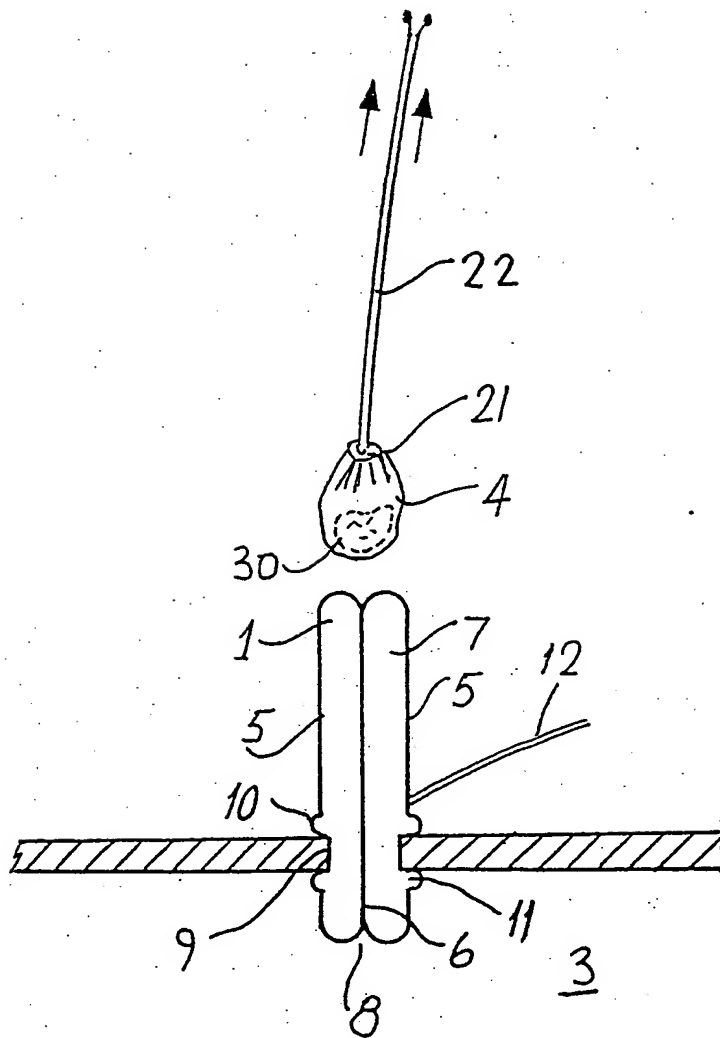
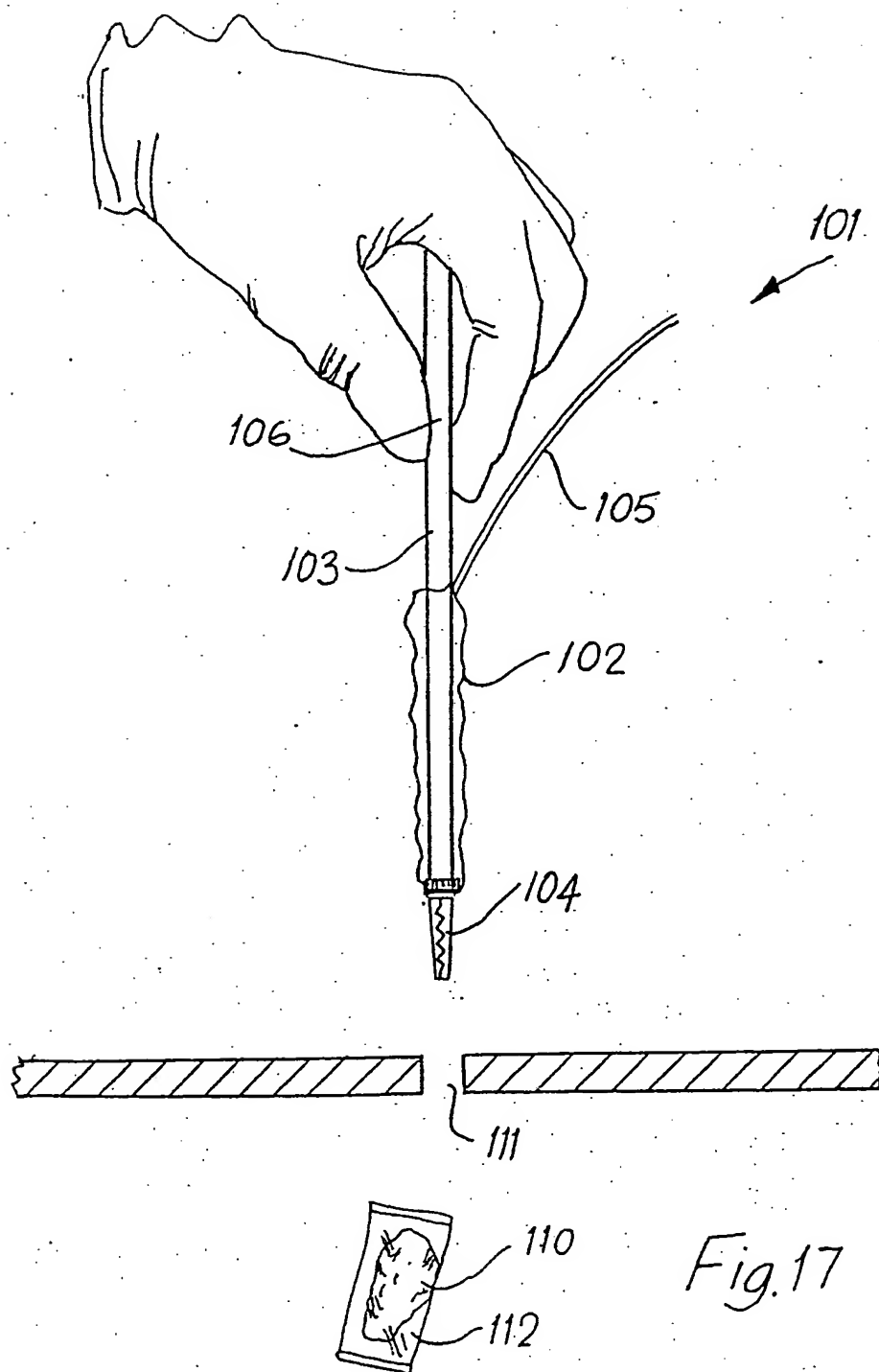


Fig. 16



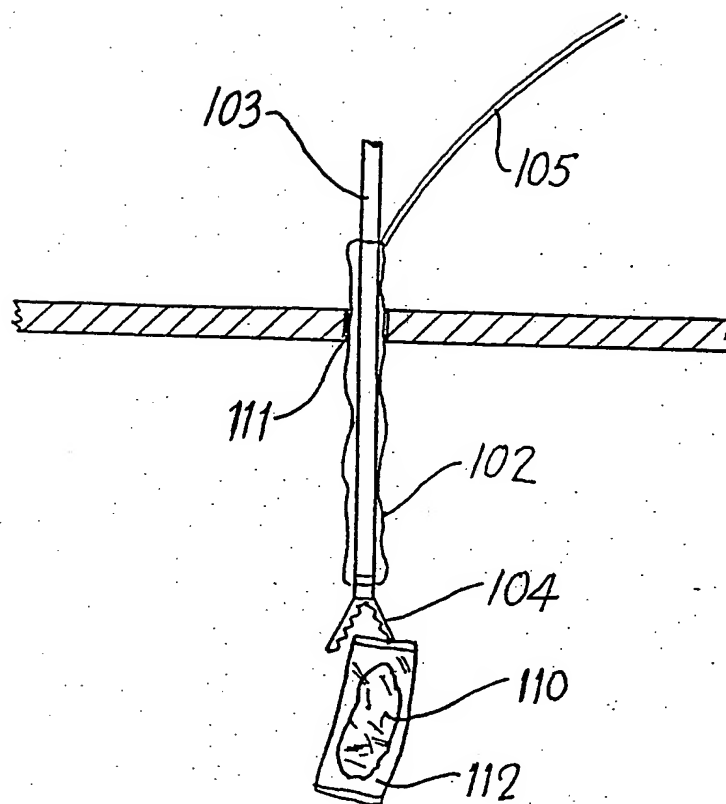


Fig. 18



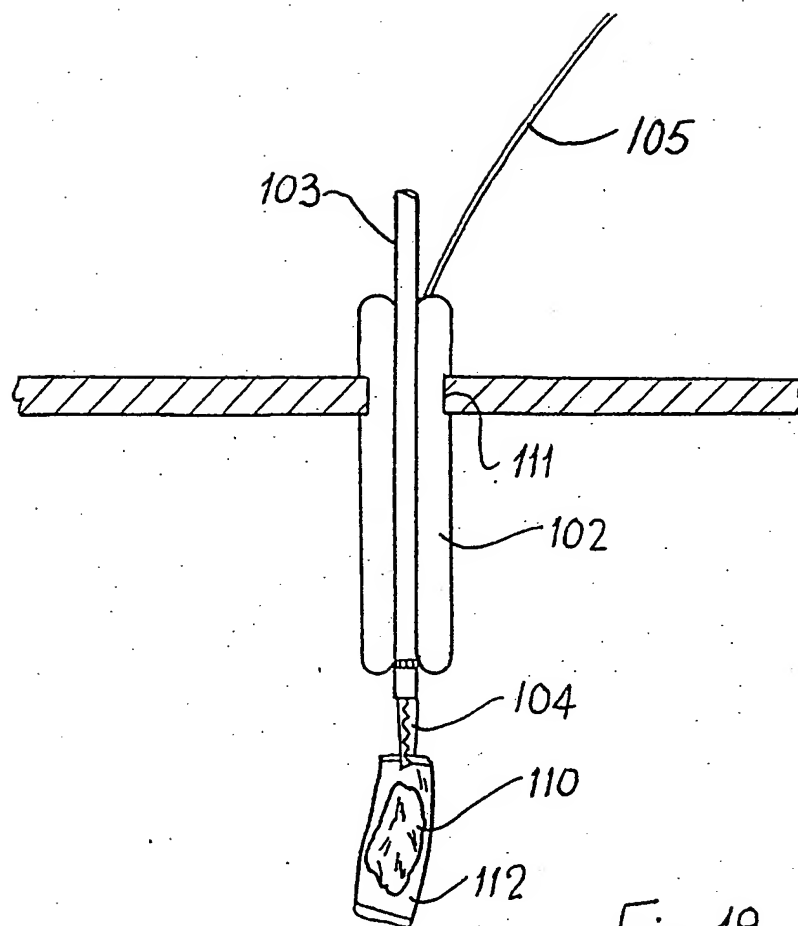


Fig. 19

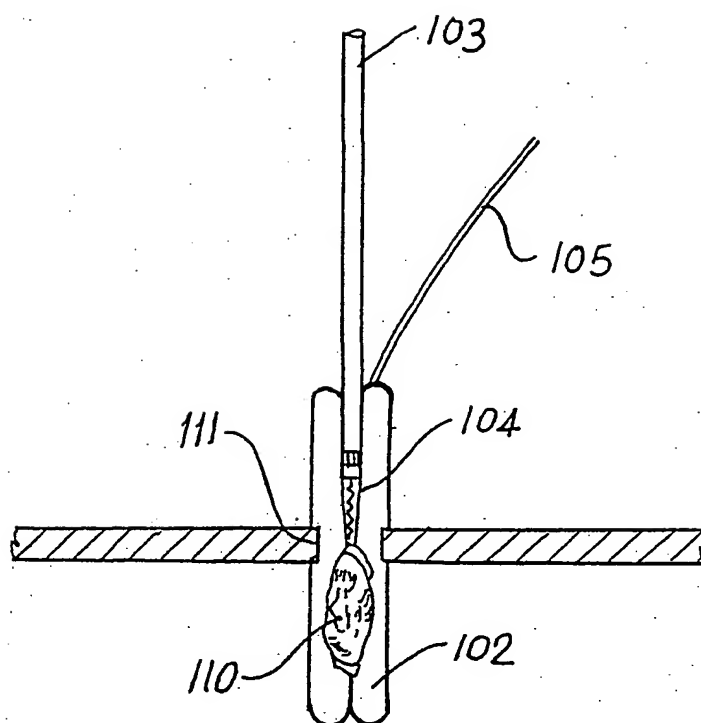


Fig. 20

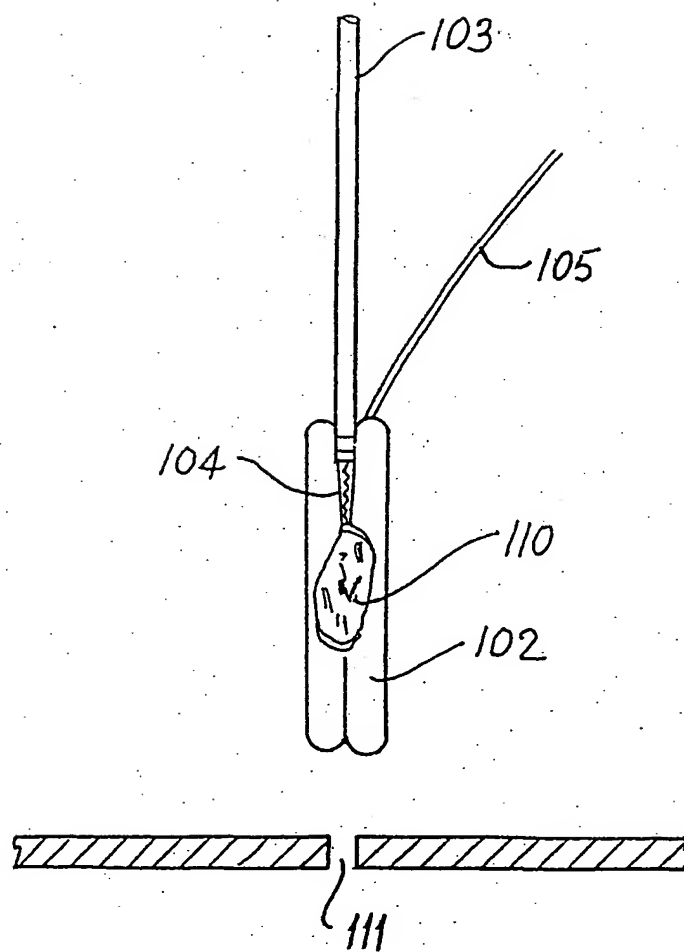


Fig. 21

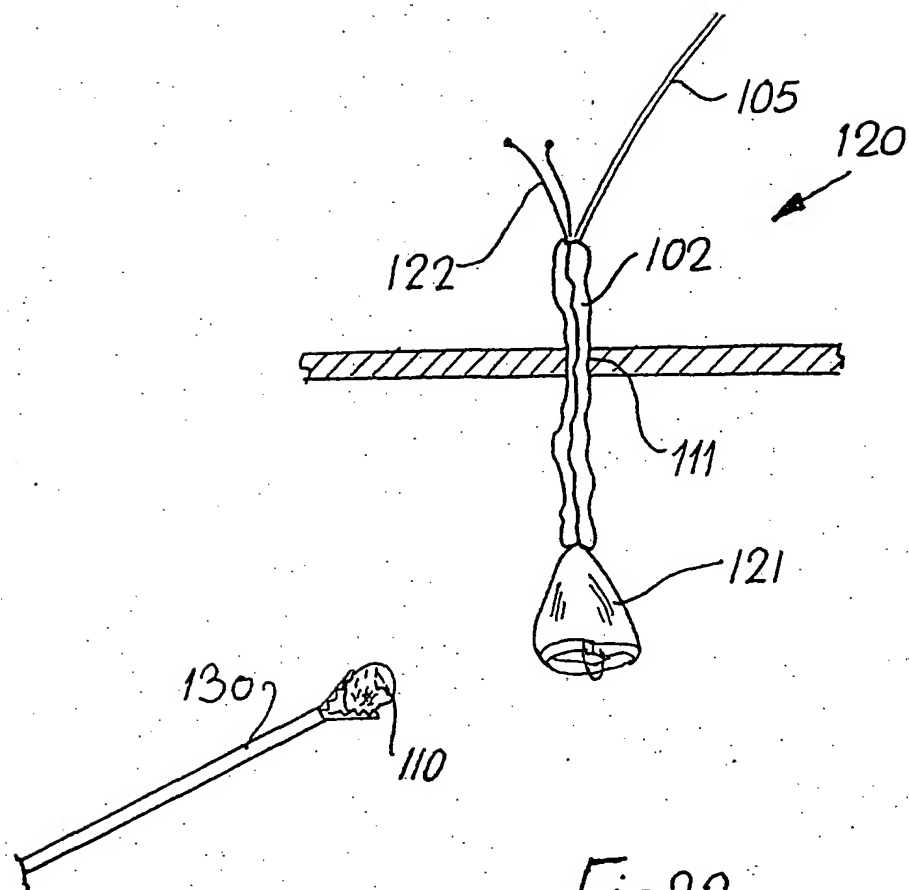


Fig. 22

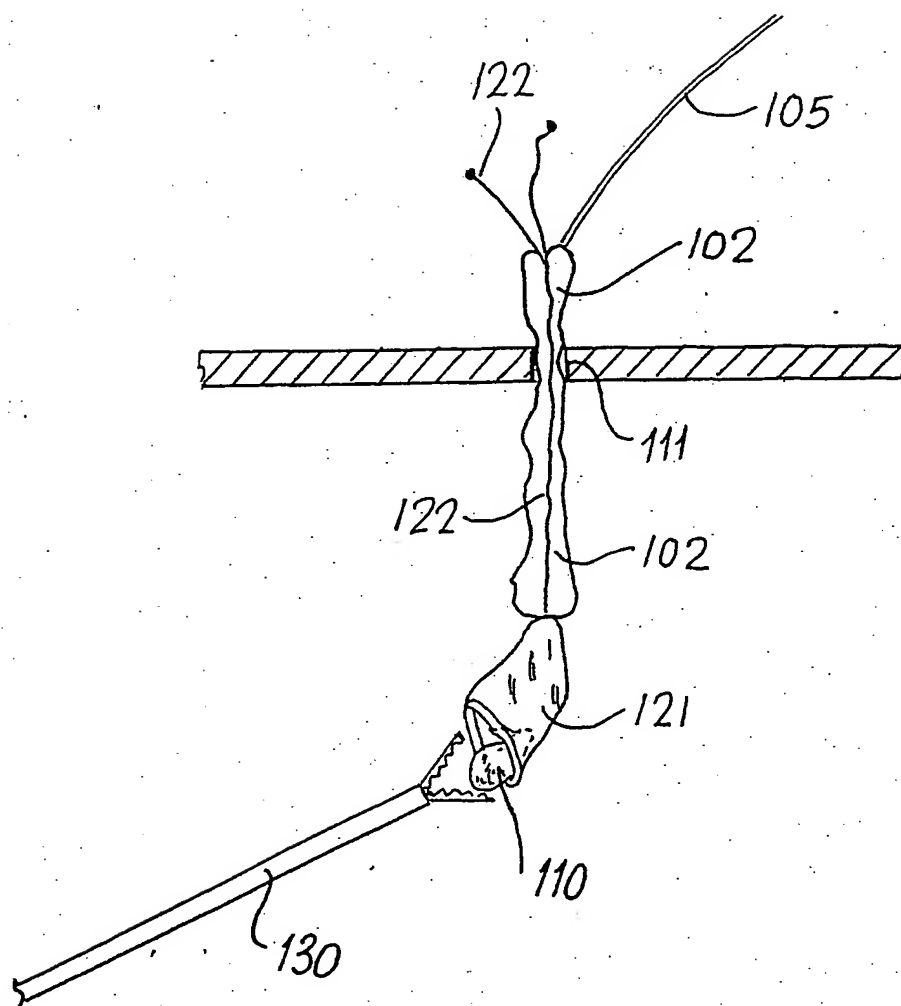


Fig. 23

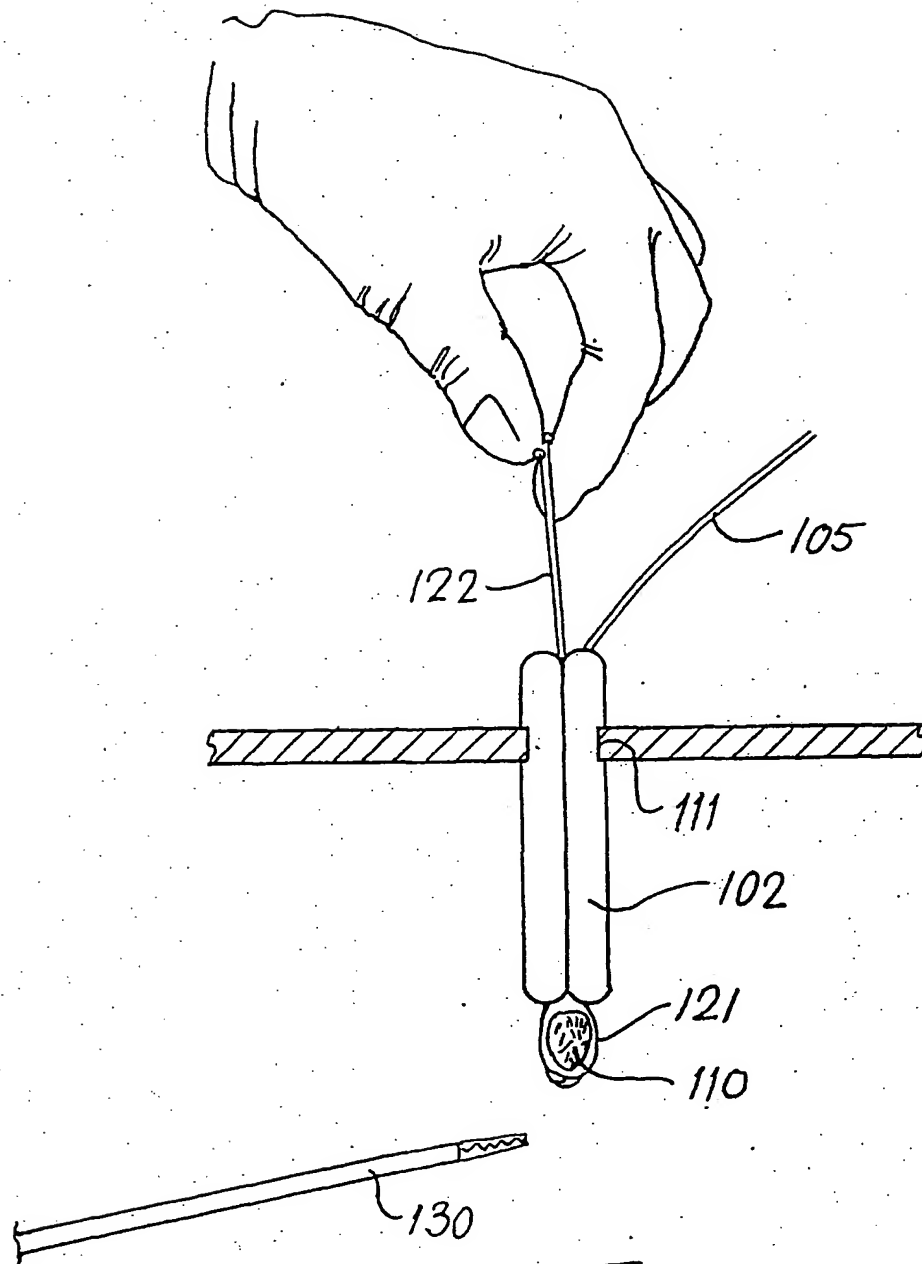


Fig. 24

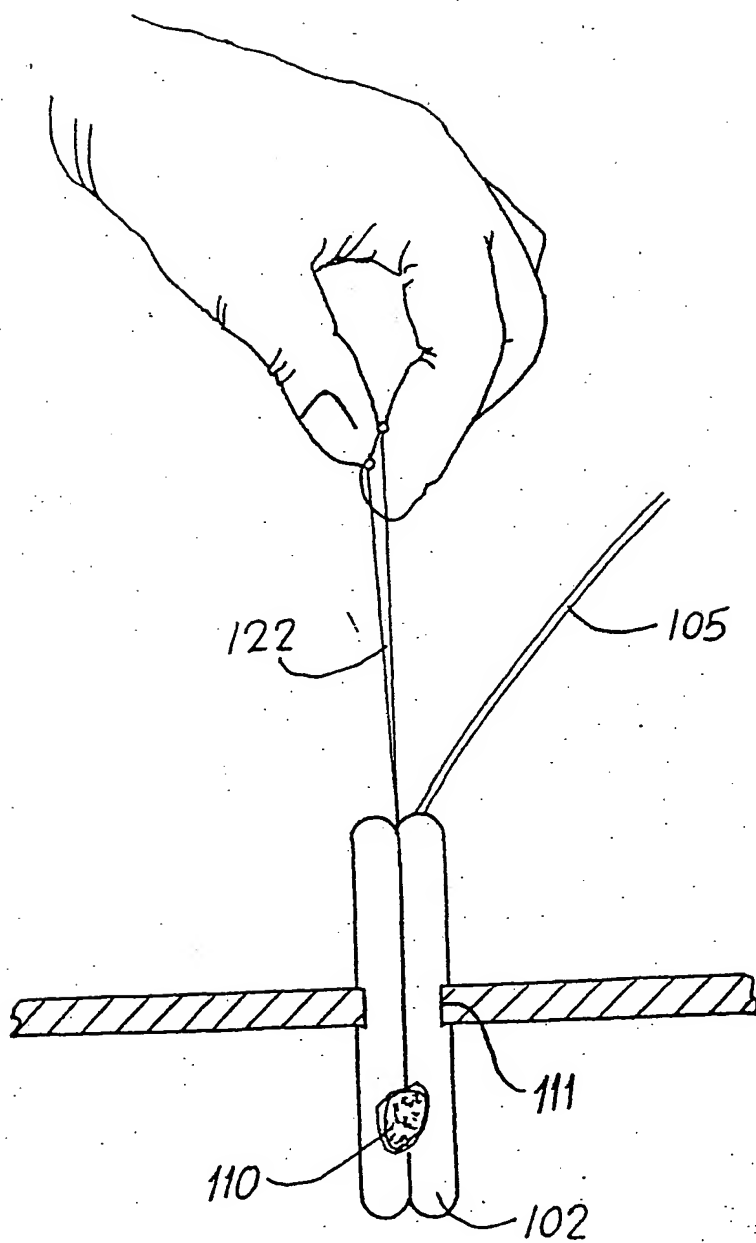


Fig.25

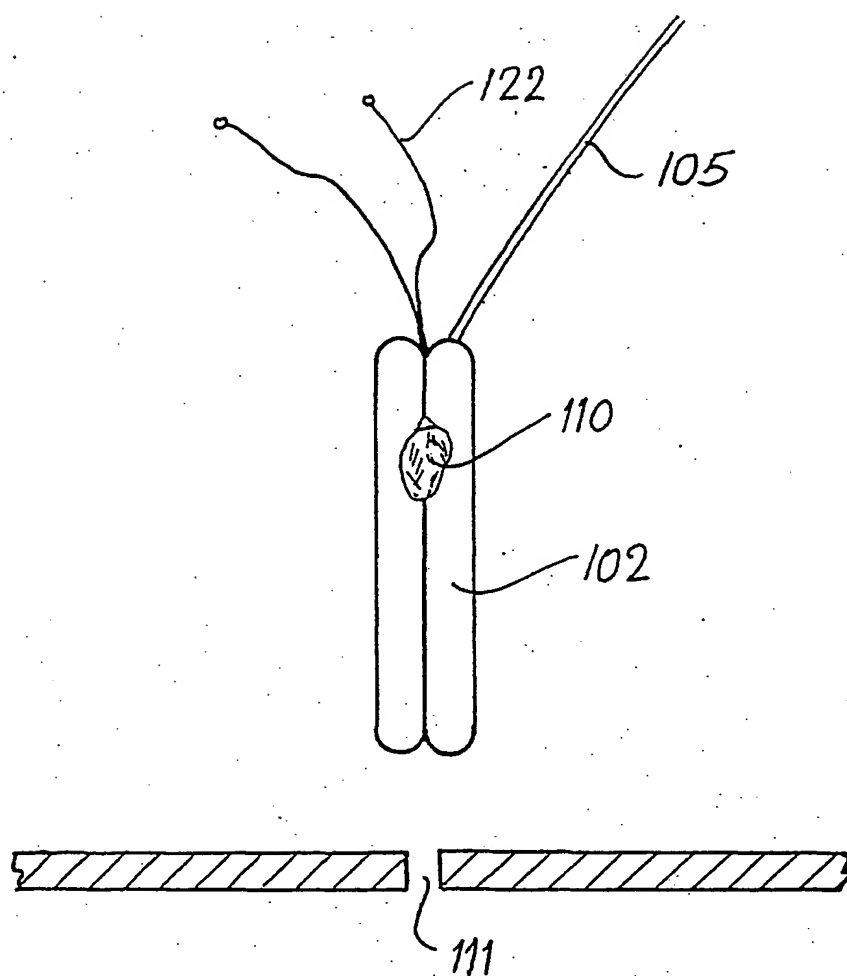


Fig. 26



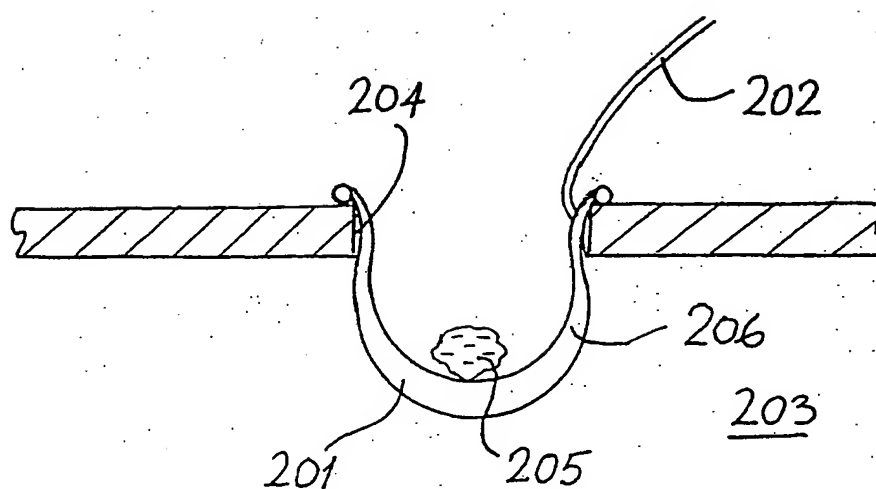


Fig. 27

## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/IE 01/00075A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61B17/34 A61M25/01

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)  
EPO-Internal, -WPI Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 200 668 A (FOGARTY) 5 November 1986 (1986-11-05)  abstract; figures 1-6 column 5, line 12 -column 8, line 4 ---	1,2, 13-18, 27-33
X	US 5 374 247 A (LOWERY ET AL.) 20 December 1994 (1994-12-20) abstract; figures column 4, line 39 -column 5, line 51 ---	1,13-15, 30
X	US 5 634 937 A (MOLLENAUER ET AL.) 3 June 1997 (1997-06-03) column 10, line 16-50; figures 2,12-18 ---	1,13-15
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-/-		

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
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- "O" document referring to an oral disclosure, use, exhibition or other means
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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&amp;" document member of the same patent family

Date of the actual completion of the international search

7 September 2001

Date of mailing of the international search report

21. 11. 01

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Authorized officer

GIMENEZ BURGOS, R

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/IE 01/00075

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5' 643 282 A (KIETURAKIS) 1 July 1997 (1997-07-01)  abstract; figures ---	1,2, 16-18, 30-35
A	US 5 853 374 A (HART ET AL.) 29 December 1998 (1998-12-29) the whole document ---	1,2, 16-26
P,X	WO 00 32120 A (ATROPOS LIMITED) 8 June 2000 (2000-06-08) the whole document -----	1,13-15

# INTERNATIONAL SEARCH REPORT

International application No.  
'IE 01/00075

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 55-74  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☒ Claims Nos.: 43, 54  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:  
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-42

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/SA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-42

Invaginator apparatus comprising an evertable sleeve.

2. Claims: 44-53

Receptacle defining a receiving mouth, and means to facilitate closure of the mouth from a remote location.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 43,54

The subject matter of claims 43 and 54 is defined by reference to the description and drawings which is not allowed by the PCT (see Rule 6.2 PCT). The claims do not define any clear structural feature or limitation. Consequently, the scope of the claim is not clear (see Article 6 PCT) and meaningful search is not possible (see Article 17 PCT).

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

# INTERNATIONAL SEARCH REPORT

Info on patent family members

International Application No

PCT/IE 01/00075

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